HIT Policy Committee
Final Transcript
March 17, 2010

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you. Good morning, everybody, and welcome to the tenth meeting of the HIT Policy Committee. Again, this is a federal advisory committee. The members of the public are here in the room and listening on the phone and on the Web, and there will opportunity at the close of the meeting for the public to make comments. Workgroup members, if you could please remember to identify yourselves when speaking and I'll begin now with having the members introduce themselves around the table.

Jodi Daniel – ONC – Director Office of Policy & Research
Jodi Daniel, ONC.

Adam Clark – Lance Armstrong Foundation – Director for Health Policy
Adam Clark, Live Strong.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Larry Wolf, Kindred Healthcare.

Connie Delaney – University of Minnesota School of Nursing – Dean
Connie Delaney, School of Nursing, University of Minnesota.

Art Davidson – Public Health Informatics at Denver Public Health – Director
Art Davidson, Denver Public Health, Denver Health.

Stephen Ondra – Department of Veterans Affairs – Senior Policy Advisor
Steve Ondra, VA.

Paul Egerman – eScription – CEO
Paul Egerman, software entrepreneur.

Tony Trenkle – CMS – Director of OESS
Tony Trenkle, CMS.

Marc Probst – Intermountain Healthcare – CIO
Marc Probst with Intermountain Healthcare.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David Blumenthal, National Coordinator.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Paul Tang, Palo Alto Medical Foundation.

David Lansky – Pacific Business Group on Health – President & CEO
David Lansky, Pacific Business Group on Health.

Gayle Harrell – Florida – Former State Legislator
Gayle Harrell, former State Legislator from Florida.

Scott White – 1199 SEIU – Assistant Director & Technology Project Director
Scott White, 1199 SEIU.

Judy Sparrow – Office of the National Coordinator – Executive Director
We have a number of members on the telephone, if you could please identify yourselves.

Deven McGraw – Center for Democracy & Technology – Director
This is Deven McGraw with the Center for Democracy & Technology.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Deven. Anybody else from the committee on the telephone? All right, with that I'll turn it over to Dr. Blumenthal and Dr. Tang.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Good morning, everybody. Thank you again for coming. As you will see from our agenda this morning, there's still a lot happening even though we don't have as full an agenda today as we often do. We thought we would give the committee a little bit of a breather by not going packed 9:00 to 3:00, but every issue on the agenda today is fascinating and complex and important. I think you will find it that, and we look forward to your thoughts on all of these. They all also reflect in very material ways the work and the recommendations of you and your working groups, so you continue to be the foundation for a lot of the inspiration and the direction of the Office of the National Coordinator and federal HIT policy.

I can't help noticing that we seem to be tilting to the left as I look around this table, or if you're in the audience, we're tilting to the right. We are a fully-balanced group normally, but today, we're tilting to the left. I don't have a lot more to say. I'll let Paul take us through the specifics of the agenda, and then we can get about our business.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you, David. The agenda as David said is a little short on number of items, but I think we actually may overflow a little bit past 1:00 it may turn out. We'll begin with an update on the strategic plan workgroup, and this is the update to the strategic plan that's called for in the HITECH legislation. Then the certification work and adoption workgroup had a very interesting hearing on EHR safety, and they'll be not only reporting on the findings that came out of that hearing, but also some draft recommendations for discussion, and I think that discussion will probably be very lively. And NHIN workgroup will continue to update us on their plans and progress towards moving towards a nationwide health information network.

The HIT standards committee, various workgroup members are going to update us on their work, and this will be a chance to sort of synchronize with the policy committee. We all know that in the statute, the HIT policy committee is to set sort of the agenda or priority, and the HIT standards committee helps follow through with the standards, so this is a good time both to update each other as well as to try to synchronize our efforts.

Followed by a report on the certification NPRM which came out since our last meeting, Tony Trenkle will present remarks on the NPRM comments, the comment period which closed just two days ago, and we'll get an update on the CLIA amendments that also were recently released. The federal government has been very active in the past month as it has been in the past year, certainly from this body's point of view, and we'll close with public comment. Any updates to the agenda?

At this time I wonder if I could entertain a motion to approve the minutes. Great, thanks. All in favor and any opposed. Very good. Thank you very much, and we'll turn it back to David.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I want to take a moment just to introduce a new member who's representing a traditional member of the group, and that is Dr. Stephen Ondra from the Veterans Administration. He is Senior Advisor to the Secretary of the Veterans Administration and has a distinguished service history and clinical history as a neurosurgeon and has been a terrific partner of ONC in a lot of activities that the VA and the ONC do together related to NHIN and the Beacon Community Program and several other things. He's stepping in to represent the VA, so welcome, Steve.

We have a hearing on patient engagement. I understand that is coming up on April 20 at the Omni Shoreham Hotel here. Does anybody want to comment further on that? Jodi, do you want to—

Jodi Daniel – ONC – Director Office of Policy & Research
Paul Tang, we're sort of just developing the presenters for that hearing, and if you just watch our Web site as we get the agenda more fully developed, we'll certainly put information on the ONC Web site.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Let's then ask for the strategic planning workgroup to give us a report.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay, you want to start, Jodi, then?

Jodi Daniel – ONC – Director Office of Policy & Research
Thanks, Judy. Good morning, everyone. We're reporting back again from the strategic plan workgroup, and we have an at least final draft I'll say of the workgroup's strategic framework that we'll be looking for public input on before revising and coming back to you, and we'll talk about next steps at the end, but what we really wanted to do today was to give some of the bigger picture focus.

We've gone through a lot of the details of the workgroup's discussion on the goals, objectives, and strategies, and at our last meeting, we actually had a great discussion trying to pull this all together and discuss how all the four themes in the strategic framework fit together. What we wanted to spend time today on is giving that big picture to the committee and getting your feedback on that before we go out for public feedback on this. That's what our objective is today.

Just to remind everyone, the health IT strategic vision and themes, like I said, we're not going to go into detail below this, the vision is a learning health system that's patient-centered and uses information to continuously improve health and healthcare of individuals in the population, identifying inherent values, the role of health IT, and the role of the federal government. There are four themes that we've identified. Meaningful use of health IT and we sort of thought of that a little broader than the statutory definition of meaningful use, but inclusive of the statutory concept of meaningful use; theme two, the policy and technical infrastructure; theme three, privacy and security; and theme four, the learning healthcare system. We're going to try to talk about how we see all of these themes working together to lead to the vision that the workgroup has discussed, so I'll turn it over to Paul.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Our national coordinator, Dr. Blumenthal, has called for a learning health system, and Dan Rome says that the best way to explain things is really to draw on the back of a napkin, so what we have before you

is our napkin or our latest rendition of the napkin. We're trying to depict what we think is meant by a learning health system. We're very, very open to your feedback. In a health system, there's a set of activities that are all conducted on behalf of and for the patients and the population, and it generates a set of results that benefits society, so let me try to walk you through that.

Front and center in that blue box is the people that this is all about. They're individuals, and they're the population at large. For those people, there's a set of services on the left, and those activities include engaging the consumers, providing care when needed, measuring the quality, using that information to continuously improve and innovate and conduct research to continuously improve this science.

As a result of those activities for the benefit of individuals and population, there's a set of data that's collected. If you apply that data and adequately protect it and combine it with best practices, then hopefully, it will result in generating new knowledge which is shown in the top half. You use that new shared knowledge to improve care, to improve outcomes, and to enhance value, and that would benefit all of us, shown on the right in the beneficiaries, patients, consumers, providers, by and large society.

If you take all of these efforts and not only deliver care to individuals, but learn from all the individual experiences, learn from the population, we'll have a better and continuously improving health system, and that's what we think that the National Coordinator meant by a learning health system.

Well, what's the role of government? The role of government is those lines below, the infrastructure. In a sense it begins with that very bottom one which we labeled theme two. That's the infrastructure, the technical infrastructure and the policy infrastructure that things have to be built upon the foundation, and then on top of that is our policy infrastructure which means all information has to have adequate privacy protection, and that's done through secure systems. Theme one then represents the software and the hardware that is used by the professionals and the patients to create a meaningful, useful information infrastructure that's, of course, the activities above.

In total this is a graphical depiction of the learning health system and the role of government, i.e. the role of ONC at least as we've depicted it, the three layers down below to support that, the creation and maintenance of that. That's our first attempt in terms of describing the learning health system.

In this slide it's a rendition of Dr. Blumenthal's *New England Journal* piece that talked about ONC's role implemented through the various provisions of HITECH, so it includes of course the meaningful use of certified EHRs in the middle. It's supported by the activities to help increase the adoption of EHRs like the regional extension centers, like the workforce training grant, and supported by the exchange of health information through the HIE, both the HIE grant and the NHIN work, and the work in the standards, all of which need to have an infrastructure of research that continuously improves all of that. Then that supports those integrated ONC programs and support the creation and maintenance of the learning health systems. That's our view of the ONC support of creation of this learning health system.

Finally, the next steps, the public listening session about this, we're going to describe the document that you have before you. It's posted on the Web. There's going to be a public listening session on April 6 where we'll present sort of a high-level summary of the recommendations for the strategic plan updates, get the public feedback, finalize the document to present it to ONC by May. Then ONC will take it through its internal processes to accept that input, develop its updated strategic plan, and go through clearance by October.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you, Paul. Any comments or observations about that framework?

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Along the top there you have enhanced value, but also new knowledge and improved care, so what is enhanced value independent of those other factors? Are you talking about cost?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
It's a value equation which is the quality over the cost.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes, Connie.

Connie Delaney – University of Minnesota School of Nursing – Dean
I think that this is a remarkable work and really commend the group. I find it interesting that with the commitment to the learning health system that under the activities on the left there isn't reference to education. One suggestion I might have for the group's consideration is an explicit consideration of activity related to education, particularly as it relates to the synergy among the consumers, patients, and provider, as well as society, and particularly as it relates to all of the work going on here and the necessary interprofessional work of the providers.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you, Connie. Education is certainly a part of what we meant by engaging consumers, but we'll try to find a way to call that out. Thank you.

Charles Kennedy – WellPoint – VP for Health IT
Comments from the phone?

David Blumenthal – Department of HHS – National Coordinator for Health IT
Please.

Charles Kennedy – WellPoint – VP for Health IT
Hi, Charles Kennedy here. I'd also like to highlight under beneficiaries, pairs and employer groups will be significant beneficiaries, maybe not directly through the care provision, but I do think the higher value care delivery will resonate with those two groups, and that could be helpful to us in many states.

David Lansky – Pacific Business Group on Health – President & CEO
This is David Lansky. I also appreciate the work of the group, and the detail within the documents, the longer framework paper is really helpful, and I agree with everything in there. There are two themes that I want to see given more visibility, and maybe you can just react to how you've discussed them so far.

One is pertaining to the value question which is essentially what's the post-era? What is the financial model for participation in this learning healthcare system, and how does ONC speak to the incentive structures which motivate participation in healthcare reengineering using IT beyond the initial stimulus funds? That obviously opens the door to lots of very complex questions about payment reform and so on, but I think it's important to speak to that either through scenarios or philosophically or as a matter of describing what features will be essential to drive the engine that we're looking at on this slide because my concern is that a lot of these ideas we've had for a long time, but the engine hasn't cranked, and we need some fuel to turn it over.

The second issue that I'll be interested in is the technology infrastructure question in theme two, and I think there's a potential to be looking in the rearview mirror technologically. If we're looking out five or ten

years strategically and we anticipate extension of current technology trends both with mobile computing and cloud computing, other platforms and mechanisms for putting information into people's hands, those could be transformative and could either enhance or undermine some of the principles that we think drive this model. I hope that the strategic plan will have a way to incorporate the future-minded technology transitions that may really alter how we think about a lot of these relationships.

Jodi Daniel – ONC – Director Office of Policy & Research
This is Jodi Daniel. In response to at least the second point, I think when we drill down into the strategies, both in theme two and in theme four, there are strategies that focus on emerging technologies and sort of monitoring emerging technologies and adapting technical infrastructure and policy infrastructure in light of emerging technologies. I think some of that detail is captured in the strategies. If you look at the document and you think that there needs to be some change there, feel free to email Paul and myself, and we can take a look at that.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes, Gayle.

Gayle Harrell – Florida – Former State Legislator
Thank you very much. Gayle Harrell. I just want to make a few comments about the enhanced value and the quality over cost component. I think as we drill down into that we really need to be very specific as to what that cost benefit relationship is and who is the decision-maker in that evaluation, and we need to make sure that that decision ultimately resides with the patient and that the patient has an integral part in what the ultimate value is for them. We don't want to get so into what the cost benefit relationship is. This can get very sticky at times in decision-making, but I think the patient needs to be very much involved in that process at the end of the road.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Yes, Adam.

Adam Clark – Lance Armstrong Foundation – Director for Health Policy
Adam Clark, Live Strong. I think that's a very important point, and I know each of us can look at the different areas of this and say we'd like to see this here, but I do want to reiterate under enhanced value that this is about informed patients, that we're bringing knowledge to them to help them make informed decisions on this.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I really like those two comments, and I think it is missing, so when we talk about learning health system, a lot was focused on the professional team, and although we were careful to include engage consumers and consumers as beneficiary, I like this new thing. I would propose that under the result we have those bullets, but we also have maybe inform patient or increase patient knowledge, but something to capture that point because I think it's a very important point. We'll have to go back and look at our strategies and make sure that that's covered. I believe it is actually. We have patient, in two of the themes have increase patient education, but it's not captured here, and it's a perfect point. Thank you.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I have a question for the group, and that is whether you've settled on a timeframe for this plan. Do you think of it in terms of 5 years or 10 years or 20 years?

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO

That's also a good question that ties into question one of David Lansky's which is what's the persistence essentially beyond HITECH. The original HITECH language, I believe, was to update the plan to include the 2011-2015, so in a sense it covers the "HITECH" era. I think we need to go back and look at what's the persistent value that ONC plays and all the regs and the infrastructure, the support that it provides. How does it continue on and support the continuous learning system beyond 2015?

Jodi Daniel – ONC – Director Office of Policy & Research
I think the workgroup has been looking at this as five years, but not just looking at what's in our legislation as far as what our strategy should be, so it's inclusive of what's in HITECH. We've had a lot of discussions about what are some of the steps that we need to take now in the next five years to be thinking beyond what's in HITECH and the HITECH incentives which goes to some of David Lansky's points. I think the workgroup has been looking at five-year activity so it'll also set us up for the next five years after that ….

David Blumenthal – Department of HHS – National Coordinator for Health IT
Sure.

Gayle Harrell – Florida – Former State Legislator
If I can make a further comment on that, I think we need to look as we go beyond HITECH where those incentives are and where the payers are in the system. We need to look beyond government that the benefits, for what we are doing go beyond government and are ultimately to the payer and the patient. We need to make sure that the long-term looks for that financial undergirding of the system to the people who are really the beneficiaries of this and that is in the long run, that enhanced value comes down to payers and patients.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Any other comments?

Jodi Daniel – ONC – Director Office of Policy & Research
I would just say we would encourage folks to participate in the listening session and hear what we hear from the public. The goal is to really get broad public input, and we're going to try to publicize as well so that folks are available. I know CMS has very successfully had listening sessions in the past, so we're trying to use that model as a way of getting broad public input and having broad discussion and leaving plenty of time for that, and then the workgroup will kind of queue on some of that public input and incorporate it into the strategic framework before coming back to this group with a final version for your consideration.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Excellent, well, thank you, Jodi. Thank you, Paul. We're now going to turn to a very different topic, and we're going to hear a report from the certification adoption workgroup on the conclusions or summary of the conclusions from the hearing that we had in this very hotel a couple weeks ago on safety of health information technology.

Marc Probst – Intermountain Healthcare – CIO
I guess Paul wants me to start this off. Paul asked me if prior to going into our slides if I'd just give you a little vignette or a little background based on my role as CIO at Intermountain Healthcare of any patient safety issues or things that we've incurred with HIT. I'm going to do that very quickly, and then we'll get right into the slides.

As we look at HIT-related issues, and we went through this whole panel which I thought was just excellent by the way, just great input by the public and by the panelists that we had, but as I look at Intermountain Healthcare, if you look at the real issues we have with HIT, very few of those issues are associated with the code that the vendors provide to us. That's a pretty odd statement for a CIO to say because typically we love to blame the vendors, but by and large, most of the issues haven't been with the code that we've received.

We do a lot of quality assurance, and that quality assurance tends to give us a pretty good idea on how well those systems work, but nothing tests the system like actual use by the end users and the clinicians. It's amazing what an end user can do to a system to make it not work, but by and large we've had good success with the vendors and the products that we've had. Some vendors are great when we report an issue. Some vendors are not so great. Some vendors actually do hide some of the issues that we will surface. Some of them are very forthright about getting the information back to us, so it's very inconsistent.

However, the majority of the issues that we've run into at Intermountain Healthcare and probably in most organizations have to do with very local issues around local conditions and configuration of the systems themselves. No one system is going to look the same. No one has a single information system within their hospital or some large integrated network such as we have, so the issues tend to be around the network or the operating system or the security software that we've put in place, the applications themselves, how those are configured, the tables and the different variables that are put in the tables, a lot of issues around the devices that are installed and the data that those devices bring into the network and into the systems that we use and even issues associated with power.

Just a real quick couple of examples, many organizations have robotics or carts that dispense medications. We had an issue where a vendor actually came in to service those particular devices, and when they came into service it, they actually introduced a virus into our system. It wasn't seen anywhere else in the system, but because they changed the operating system on those specific devices, they introduced a vulnerability that then received a virus that impacted every one of those devices. In fact, for a period of time in those hospitals, we couldn't dispense medication from those particular cabinets. That wasn't necessarily the code. That was the environment. That was the conditions of the organization we were dealing with.

Other issues that we've come in, they're completely uncontrollable by a specific vendor as power. If you're in the OR and you're doing a procedure in the OR and you're dependent upon a screen that's got an image on it and power goes out, and that could be in many locations. That could be at the data center. The power goes out where the actual equipment, the processors are, or that could be the power within the facility where the monitor is or even on the network along the way. You could have patient safety issues, so the threat of issues is huge that we're trying to deal with.

I think having an ability to quickly disseminate information around problems is key to what we're talking about, and I know Paul's going to talk about that in some of the recommendations in the comments that we heard. Within our own organization being fairly large, 23 hospitals and a lot of clinics, we have daily calls to disseminate information around the systems in the problems that we had.

The one issue that I gave you around the cabinets and the medication, that was an immediate blast out to all of our organizations telling us that that issue existed, and we were able to prevent further problems or further challenges because that communication happened quickly, and we were able to get that across the many organizations that were involved. I think having a safe, rapid approach for disseminating

problems is something that's key to our ability to react to HIT issues that could produce patient safety problems is key to what we're talking about.

I also think there's a lot of local responsibility because every organization is unique. No one's going to have the same IT environment, whether that's the operating systems that we're dealing with, whether that's the application code that we're dealing with with a specific vendor, or whether that's right down to the various security and privacy and other tools that we use riding on our networks, even to the monitoring. Every organization's going to be unique, so there is a local responsibility to HIT safety that our vendors simply aren't going to be able to keep up with.

I think this ability to have a local capability is part of the infrastructure that needs to be in place as we look forward to what we're going to have in place for HIT safety as we talk about some of the recommendations and some of the comments that were heard. This consists of tools. This consists of processes and organizational structures that allow for the communication of this information.

My last point will just be a quick story. I promise, Paul, and then I'll turn it over. It's not a joke. It's actually not. Thirty years ago I was a missionary in South America, and while I was there I had the opportunity to work in some pretty remote villages, and these villages, they were small. The streets were small. The streets were mud, and there were huge ruts. When it rained it was pretty much inaccessible. There were no traffic signs. There were no lights, red lights and green lights and those types of things. There were no traffic police. There were a lot of infrastructure pieces missing.

I was thinking I'm sure the people in those villages would love to have red Ferraris to drive around. They could move a lot quicker. They're a lot more comfortable, and they're a lot more fun, but if we were to put red Ferraris into those cities too quickly without the appropriate infrastructure in place, without repairmen, without tow trucks, without all the pieces that were needed, without police to protect the speed or speed limit signs to keep people under control, what you have is cities full of red Ferraris stuck in the street, and not even the carts and the horses could get through.

I think one of the bigger things we heard throughout this whole discussion around HIT safety was that if we do this too quickly without the right infrastructure in place, without the right processes, procedures, and those things in place, we could introduce a lot of HIT safety issues just simply by doing it too quickly without the right knowledge out there. With that, I'm going to turn it over to Paul.

Paul Egerman – eScription – CEO

Thanks a lot, Marc. I'm Paul Egerman. Good morning and happy St. Patrick's Day to everybody. I'm going to take you through a series of slides that describe our hearing and the various things that we learned. As you could tell, what we're really talking about is sort of patient safety risks. Fundamentally, these systems actually improve patient safety, but this sort of like the other side of the coin, sometimes when things don't quite go right.

This is a list of the individuals who are part of our workgroup. I'm very proud of this excellent group of people and say thank you. They did a terrific job. There's a number of people listed, but for some reason it did not include Jodi Daniels name, and Jodi also participated in our workgroup in a lot of ways, so I say thank you for your help, Jodi, also.

This is a list of the people who presented at our hearing, and one of the great parts about working on this policy committee is we have the national leaders come in to talk to us, and so these people are all experts in their areas and know this entire area of patient safety and risks and hazards extremely well. They've done terrific work in the area. What's interesting is in addition to presenting to us, they continue to be

engaged. They are participating in our workgroup calls. They are commenting on our presentations that I'm making right now. They review the materials, and they're sending emails. They are correcting my mistakes which I really appreciate, but they feel very passionately about this issue, and it is a very important issue.

I'm going to talk a little bit about what we learned as we went through the entire process. What we learned is in some sense similar to what Marc just said. There's a lot of anecdotes about what is going on, and there's a lot of individual experience that is very valuable, and when you hear some of these anecdotes, sometimes it's really sort of scary stuff to hear this is what happened to a patient, and it's very troubling, but it is actually not a lot of formal studies that are broad-based that tell you a lot of data about just how severe is this and how prevalent is this.

There were two sources that we looked at. One was a study done in 2007 by Dr. Joan Ash out at Oregon. It was actually a great study because she surveyed like 150 hospitals. She was really looking at CPOE systems, and she determined that pretty much every hospital that she surveyed had some patient safety risk issues, had some issues with problems or errors, but they tended to be minor and tended to be caught by intermediaries, so that was her conclusion from her report.

We also have data from the FDA, although when we looked at the data from the FDA, it took us a while to understand it. The FDA data, about two thirds of the data comes from PACS systems, from radiology systems because they have mandatory reporting, and that sort of skews the data. It also indicates something else. If you look at the title here, we're talking about HIT patient safety. In other words, this is broader than EHR systems. We're talking bout PACS systems, retail pharmacies. There's a whole range of systems that we're involves with. A lot of heartfelt and very important comments are being made, not a lot of broad-based studies in this area, although a few.

It's important to say that as we went through all of this, there's complete continued confidence in HIT and the effectiveness of HIT systems. There was not one single presenter who said these are dangerous systems, don't do it, and everybody views this as very important systems that fundamentally by themselves inherently positively impact patient safety.

There are just a lot of areas of concern to make sure that they're done correctly, and there's also areas of concern that maybe the full potential of these systems aren't being realized. We want to talk about some of the areas of concern, but one concern that clearly came also from the hearing was a sense that a lot of physicians, a lot of clinicians, a lot of nurses feel frustrated. They feel they have issues that nobody's listening to. They're raising issues, and nothing's happening, and they're sort of living with systems, so there is some built up frustration there that's also important to address.

We look at the areas, and there's a lot of ways to break down where the problems are, but we decided to break it down in four groups. The first group is this group called technology issues which is what you normally would expect when you look at something like this. You expect to see software bugs, and those are definitely present and other things like calculation errors where the dosage might be calculated incorrectly. While they're definitely present, as Marc said, they're actually the minority of the cases that we looked at. It turns out when these are addressed, these are discovered, the hard part is sometimes discovering them, but when they're discovered, they tend to be fixed pretty rapidly, and they're fairly easy to address.

The next category is the category that is most interesting which is I called it complex interactions of people and technology. Basically, this is where you get into some of these issues like usability and looking at a screen, and does the screen make any sense or is it possibly misleading? To pick up on

what Marc said is, is sometimes things make sense when you look at it in isolation, but how does it really work in operation when you've got people who are very busy and stressed out and doing a million different things. How is it working? Is it confusing? Is it working right? Some people call this, on the Internet they're calling it having meaningful views in terms of a meaningful picture of what's on the screen, but there are also a lot of aspects to it.

There is, for example, there is an issue that we looked at called alert fatigue where in a lot of these systems too many alerts just show up to the clinician, and so the clinician gets used to ignoring the alerts. When they get used to ignoring the alerts, then they ignore something that maybe is very important. There are issues of alert fatigue, but also, we came to learn that if we looked at it just in terms of a clinician looking at a screen, that was also too narrow a viewpoint.

There are lots of interactions with other workflows and other things going on, so Connie, you and I were just talking about medical administration, and that was a great example where you have situations where nurses have to login to a medical administration system and do something. Then they have to log into another system and do something else. They have to have two or three or four different user names and passwords, and when that happens at best it's a difficult workflow, but what tends to happen is the nurses start to do things that undermine some of the safety features. If they have to login one place, then login something else to work on the same patient, they'll go to the first place and they'll do five patients at once. Then they'll go to the next place and do five patients at once. Once they do that, you open the opportunity for an error. These things get particularly difficult.

I think it was Ross Koppel told us this story where the medical administration was somehow in a refrigerator down a flight of stairs, so nurses were expected to go down a flight of stairs, do something, take a drug up to a patient, barcode it, then go back down the flight of stairs again for the next patient. They wouldn't do that. They would just grab all the bar-coded wristbands, take them off the patients, run down the stairs, get all the drugs, and then put them back up again, but once you've done that, you've undermined the entire process.

The concept here though is these are really complex interactions. There's a lot going on here, and picking up on also what Marc said, a lot of it is local. In other words, what may exist in one location may not exist other locations, although it probably exists someplace else in the country, but there are a lot of different issue. That was also a category of problems that we looked at.

Training and implementations, a category of problems that we also looked at. In one sense it's obvious, but in another sense it's a challenge. Marc just talked about his environment where he has 23 locations. An institution like Intermountain Healthcare with 23 locations has a constant flow of new people coming in, new physicians, new nurses, new pharmacists. It's a constant flow, so the training challenge is significant. It's a significant challenge in how these systems are set up.

The fourth area we looked at is interoperability. One of the presenters called it a vexing problem which is either a good statement or an understatement about interoperability, but interoperability is a clear area where, a source of patient safety problems. You go back to CPOE systems or any kind of decision support systems, those systems are inherently data sensitive. If you have the right data, it makes the right decision. If you don't have the right data, then you don't have a good decision, so interoperability issues are really critical.

It was very interesting. As we did our work, one of our presenters was Jeanie Scott from the Veterans Administration. Two or three days after she presented the VA had some big publicized event with interoperability between the VA system and the military health system, and so Jeanie was terrific because

she sent us information about what that whole experience was like, and what she did was great because alerts were issued, and that was helpful from a standpoint of learning.

That was great, but it also shows a very interesting thing which is it shows how much of a spotlight is being shined on this whole area. Fundamentally, it's a relatively new thing that anybody cares that an interface doesn't work, and so it sort of shows that there's a really big spotlight on what is going on in all of these different areas.

Now, if you look at these four issues, the main point I want to make as you look at these four categories is the last three out of the four involve multiple factors. In other words, three out of four of these issues, this not about a single software system or a single vendor or a single malfunction. Those exist. I don't want to tell you they don't exist, but three out of four are multiple factors.

It's also just not the case if you look at these multiple factors that you think that if everything worked okay we wouldn't have this problem. In other words, there's sort of an assumption if you all the technology worked okay, we wouldn't have this patient safety problem, and that's not correct. There are tons of issues in terms of the medical administration for example, tons of issues that are completely independent of technology. That's an attempt in a very quick way to tell you a little bit about what we saw in the hearing.

Now, the real question's what are we going to do about this, and I mentioned the list of presenters we had. We're also influenced by a talk that Captain Sully Sullenberger gave at the NHINs conference. Captain Sullenberger being the U.S. Air pilot who is an American hero, landed the plane in the Hudson River, and he talked a lot about the FAA, and healthcare should do what the FAA does.

In some sense we thought that was a pretty good model for how to address these things because the FAA system is built on the concept that everybody is focused on one thing which is patient safety, so we thought that that was a good approach. Our approach is similar to that. We have what we call our preliminary recommendations. We're calling this preliminary because this is a very important topic, and we're trying to get as much feedback as we can, so part of the goal in presenting today is to get feedback from this group and hopefully to stimulate feedback from the public, but this is a description of our preliminary recommendations.

There are a number of parts to it. You see the underlined words. We want to establish a patient-centered approach to safety, and then we say it's consistent with the National Coordinator's vision of a learning health and healthcare systems, so it's consistent with the presentation we just had about the learning healthcare system. This follows entirely from the principles that were laid out in that concept.

The next bullet sort of says that the emphasis of what we want to focus on is preventing unsafe conditions or hazards and near misses, again, a little similar to the FAA. In other words, we don't want to just say we're going to look at the egregious problems that occur or the errors. We want to say what are the unsafe conditions and how can we learn from them.

In order to learn from them what you see in the next bullet, and this is sort of like a headline of what we're recommending is sort of a national transparent information system, so a national information system that can give us the data we need and to use for evaluation analysis and also for the dissemination that Marc just talked about. Then we also put in our goal the statement that Marc also mentioned, though, to really achieve the goal, a culture of improvement needs to be created by each healthcare entity. To do this right there needs to be that cultural improvement locally within each healthcare entity. In support of this goal, we have a number of recommendations that I'm going to walk you through very briefly.

The first one relates to patient engagement, and this probably can be talked a little bit more about on April 20 when Paul Tang does his hearing and discussion about patient engagement, but we were influenced by comments made by David de Bronkart who's known as e-Patient Dave on the Internet who talked about the role patients can play in this process, and he actually talked a little bit about another example in credit card billing. When consumers got access to their bills and could easily look at a single line item and question the line item, the industry basically straightened up their billing really fast. The idea is that patient engagement can play a major role.

We introduced a new concept if you read through the detail about what we're saying about patient engagement which was families having access to inpatient medication lists because that was an area also where we determined there was some patient safety issues and some interesting challenges. This is an area I suspect that we will have comments. We want to invite comments because we made some comments in these areas, but we made them from the standpoint of best practices. We did not say anything about certification for patient engagement because patient portals has not been an area that we've really approached so far. This could be an area where people might want to ask us to go a little different, a little further.

Second place where we have recommendations is training and implementation. It's influenced a lot by Scott White's comments, but basically a recommendation to include patient safety and actually patient safety reporting as part of the training process to train clinicians as to how to report when there's a patient safety problem and what are the avenues that they can report their issues.

I'm going to do the next two together. The next two together is called before like the headline, but basically, we are saying establish basically a national database of all these issues of near misses and hazards in a structure called a patient safety organization. … patient safety organizations already exist, and we're saying that there are three or four different inputs into that that healthcare organizations and hospitals, eligible providers can submit their incidents or their conditions to the national database. We're suggesting making it a stage two meaningful use recommendations, that that be a requirement for stage two of meaningful use, that they would have to submit it. Clinicians can also submit confidentially, though, so that it would give capability for a physician or a nurse or any clinician to submit confidentially. Patients can submit, and also vendors can submit.

The other recommendation, the clinician feedback button is really intended to make it easier for clinicians to report issues. It's simply to facilitate reporting. The concept there is that if a clinician's at a screen and something's confusing or misleading to be able to push a button, sort of capture all the information about that, and automatically report it as opposed to what they have to do now is somehow either write it down or something or tell somebody later, and so you lose a lot of information. This is to try to make it easier to report.

If you look at the combination, I'm trying to make it easier to report. Making it part of stage two meaningful use, we'll have mandatory reporting from the healthcare organizations, and we also want to have training to make sure people know how to do that. That's the combination in terms of reporting and establishing the data.

There's also a recommendation on certification to include vendor customer alerts. This responds to a comment that Marc made where he talked about vendors that are sometimes uneven in terms of how they handle this issue, but if vendors are aware of alerts, the vendors need to be notifying all of their customers, and we wanted to include that along with some other issues around basically development processes as certification criteria.

The final recommendation is a best practices recommendation that relates to implementation and also how one can achieve and record these incidents internally. There's a great tool Jim Walker developed at Geisinger. It's a hazards evaluation tool that is discussed in the best practices section.

Those are the preliminary recommendations. Again, we're soliciting and inviting feedback on all of these issues. We have a number of open questions that I'm going to go through very, very fast, although, again, some of these questions we started discussions on and some of these we haven't even started.

The first one is as we look at the structure of what we're talking about is do we need some oversight function. Do we need like an NTSB-like entity, and so this is an issue that we are considering. We're also wondering if maybe that is an issue that we should consider at all, though. In other words, is that appropriate for our workgroup? Is that something that ONC should be considering? That's an issue.

There's an issue about what's the lower protection. There are interesting issues about the role of the accreditation organizations like JCo [The Joint Commission]. There's a question that we have not yet considered, but we'll be talking about is whether or not something special is needed for small physician groups and rural hospitals or safety net institutions as we go through this process.

There's an issue that Marc raised about the speed of implementation for stages two and three, and the final issue is very interesting is sort of the role of FDA regulation in this entire process. This is an issue that we started some discussions on, and I would tell you first that Jeff Shuren and the FDA has been extremely helpful through this entire process. They've given us data. They've answered questions. They've made people available.

It's really been terrific, and the FDA is of course an organization that there's I'd say trepidation about in the healthcare industry. People get nervous about FDA. It's right up there with like IRS and SEC. Marc said CMS, but I would never say that, Tony. FDA, there's some trepidation about it, but they have a lot of knowledge about how all these things work, and I think there can be some interesting opportunities for collaboration too and some very creative opportunities … on patient safety, but even in the long term we start talking about … research and relationships that might have to postmarket surveillance that the FDA needs to do. There are interesting opportunities there.

Our next step is we're asking you all for your feedback on what we said so far. We have two more calls. We're working very hard. This is a hardworking group. We have calls on March 25 and March 29, and we hope to meet back here in a month, April 21, with a presentation based on all of that, so what comments do you have?

David Blumenthal – Department of HHS – National Coordinator for Health IT

Thank you, Paul and Marc. I must say that every time I think you all have done collectively, the working groups have done a superlative job, you then exceed my expectations the next time, so congratulations on a very thoughtful processing of an extremely complex area. Anyone who has wandered in the wilderness of quality improvement and patient safety theory and practice for decades as I have will immediately find what you've been saying incredibly evocative because what you did that was so important I think is to immediately focus in on the whole spectrum of issues that are at work and seeing this in a systemic framework instead of a technological framework. Though we are the health information technology policy committee, we have both the word technology and the word policy in our title, and we have succeeded, I think, in avoiding a threat which is to focus on the technology rather than on the policy, and I think the policy is really critical.

I have a couple of questions, and one of them has to do with the epidemiology of safety hazards. You had four fundamental factors that you thought were at work, and the question that immediately comes to mind is do we have any reliable information on, and I think you said you gave us a qualitative sense of that, but any reliable information on the proportion or importance of errors that are associated with the technology as opposed to all the other things that are part of the environment of the technology.

Paul Egerman – eScription – CEO
It's a great question, and my answer, I guess some people might argue with my answer, but my answer is no. I don't think there's good data that tells you where it is. It's actually very hard to evaluate the data sometimes, so you may say there's a problem with this decision support system, but you sort of peel back the covers, and you just go to the problem there really was an interoperability problem at the core of that issue, but then if you peel back the covers on the interoperability problem, you might say the real reason we had this interoperability problem was you had duplicate patient records, and that was because you had a procedural problem at two different sites, the dictation was registered twice, and that should not have occurred. It's a great question, but it's exactly the kind of thing we need more evaluation of.

Marc Probst – Intermountain Healthcare – CIO
I think within closed systems my environment would be one to look at. We don't even track it that way. I think we could probably figure out that information, but we've never really looked at it, what's systemic versus what's specifically code.

David Blumenthal – Department of HHS – National Coordinator for Health IT
The second question if you would just allow me a followup, from the certification and adoption working group, you helped us think a lot about certification and the certification process. I don't know if you've given any thought to post certification surveillance as a source of some of the information that might be helpful in this regard. That is the intersection between the certification process and the information and improvement that may make safety of these systems better.

Paul Egerman – eScription – CEO
That's a great question. Actually, we've given a little bit of thought to that issue, but probably not enough, but fundamentally, you're exactly right that the certification process does include a surveillance capability, and that surveillance capability is very important. The surveillance capability initially was about you need to make sure that people really abide by what they were certified to do. Sort of like an issue of you buy a car and it says it gets 20 miles to the gallon, but you try to drive it, and you can only get 15, so you want to make sure these systems really work in the field the way they're tested to work, but the idea also that it would have feedback into the certification process makes sense.

As you go through the detailed recommendations, we also were hoping that data from the national database would have an impact on certification too, that that would be the real key. You'd get this market surveillance process would be to say here's what's going on and because of that we're going to alter our certification process. That's what we were hoping for.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Gayle.

Gayle Harrell – Florida – Former State Legislator
Thank you very much. Gayle Harrell. One of the things that you did not bring up and did not discuss that in many discussions on patient safety we have had in Florida and in trying to pass legislation on patient safety is the liability issue, and you really did not address that. Can you give us some comments and thoughts on what you would propose to really make the system work? You're developing, especially with

a database and things of that sort, a goldmine for … lawyers, and the potential for how are you going to write a system like NTSB unless you have some immunity, some reduction in liability, and things of that sort if you really want a system to work and you really want the reporting mechanism in there, especially with the near misses. Have you looked at what you're going to do to address the liability issues?

Paul Egerman – eScription – CEO
Sure, it's a great question because you really can't look at this issue without considering that, and the way we sort of tried to deal with that is in a number of ways. One is by focusing more on hazards and near misses. What we're hoping is you're focusing on areas before there's an issue liability and reporting it, so that's one way we tried to address it. The other way we tried to address is to make sure that there's a capability for people to report issues confidentially so that to the extent that if there's some fear of liability that's preventing an organization from reporting it, again, since Marc's sitting right next to me, look at an organization like Intermountain Healthcare where you've got thousands of employees that hopefully somebody will be willing to report the issue. There might be other ways to address that issue, though. I don't know if you have some ideas. I don't know if you want to speak to that issue, Marc.

Marc Probst – Intermountain Healthcare – CIO
No, go ahead, Gayle.

Gayle Harrell – Florida – Former State Legislator
I really think that this is something that needs major discussion because if you move forward in trying to implement the kinds of things that we're talking about which I think are valid concerns and need to be discussed and need to be implemented. I think you've got to consider that in everything you do. How are you going to make sure that ultimately the system works because reporting, especially near misses, can be very, very helpful, but it won't happen in reality unless you have some degree of immunity or the system is built so that people are comfortable doing it. That's what NTSB works on, and you've got to have that same kind of thing. It's very difficult to do, but it needs to be addressed.

Marc Probst – Intermountain Healthcare – CIO
Yes, and whether it's HIT or whether it's just general patient safety issues, having a safe environment to be able to report those in so that you can get the information into the hands of people that can change the system or the practice is pretty important. We talked about that quite a bit that we have to be able to have that kind of environment. Now, we don't have the answer yet, but we would agree with you.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Paul.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
A response or my question.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Your response and your question.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Good, thanks. Gayle, a very important issue. One of the things that Paul Egerman mentioned is the FAA model of where you have, and essentially they do have statutory protection, not against negligence, but against, let's say if you were speeding at 36,000, and you report that, then you're protected if you do it within a certain time limit. There are a lot of built-in incentives, one to get the report, but two to protect the process. Likewise, there is legislation that creates patient safety organizations that also have similar

protections, not against malpractice, but against prosecution as far as reporting these near misses, so there is some of that already built in. That's why we piggy-backed on that.

My question then is, I certainly agree with you that the incidence of software bugs per se is relatively low, but I think one of the biggest risks you face is when it is "working as designed," but the way it is designed sets this up as a systemic risk for human errors, and I think that the bigger problem is these complex screens when we really would like, the objective is to focus the human on the important components on the screen. I think the challenge before all of us is how do we in a minimally invasive way create a safe learning system where both the users and the vendors can contribute to this learning process of reporting the oops and the boo-boos and learn from it on behalf of the entire system.

If in the absence of a safe place to do this or in some sense a mandatory reporting, then let's say you have a well-intentioned vendor, and that vendor steps forward and does report. Well, ironically, they may actually be disadvantaged by trying to advance the field. It seems like we need to create somehow a level playing field (that's where the mandatory comes in) where everyone is required to report, and then your NTSB idea, then there is a due diligence and a drill down to figure out what's the underlying cause, and is there something that the entire field can learn from this series of events or population event. I don't know what that answer is, but it seems like there is a mandatory level playing field component to that. The postmarketing surveillance, I think all of us are somewhat allergic to the premarket approvals because that really has the risk of competing innovation for sure, but the postmarketing surveillance and the mandatory aspect of that may be some of the components we need to have in our solution.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Mike Klag.

Mike Klag – Johns Hopkins Bloomberg School of Public Health – Dean
Mike Klag from Hopkins. As you know better than I do, errors occur because systems allow them to occur, and you made the point that the IT system is only one of a number of systems, so I wonder about the wisdom of separating out a separate process to look at IT rather than trying to fold it in ongoing processes that institutions have to ensure quality. That's one.

Two, I just want to add to the anaphylaxis about the FDA being involved. As a former Vice Dean for Research, I dealt with the FDA all the time, and the FDA has this regulatory role to protect people, and so they look at system issues. They look at whether you have processes in place, but they look for the individual who made the mistake, when that FDA letter gets issued and you Google it, the first thing that pops are the paid ads for attorneys to sue about that. I think the FDA isn't the right model because I don't think they can do what we need them to do in terms of ensuring that the system works and that blame is assigned to the system and not individuals unless there's real malfeasance.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Neil.

Neil Calman – Institute for Family Health – President & Cofounder
Thanks. I guess there's another concept that we're talking about that I think we could introduce here which is the area of competency testing. The systems are sort of installed, but we don't really do anything to test the competency of the user. The other side of Paul's comment is that sometimes the systems really do great and they work great and they're designed well, but the people that are using them aren't appropriately trained, and they haven't been tested to be able to use the systems competently.

If you go back to the FAA model, somebody comes out with a new plane they don't just stick an existing pilot in a new plane and say, here, look at all the fancy whistles and stuff. People have to be trained and tested in every single type of airplane that they fly, and all the new equipment gets done exactly the same

way. When something new comes in, people are trained in it, and they're competency is tested. Before you go around requiring people to report things that don't work, one of the things we should do up front is at least make sure that people know how to do that well.

There are two areas of competency that I think we should consider. One is the competency of the vendors in installing the systems and teaching people safely how to use them at the get-go. There are all kinds of ways that the systems can report on use.

For example, there are ways that the systems can report how long does this take for a provider to finish a note from the time they start a note. Well, if that's two hours, there's a real problem there. It means somebody jotted down a few words, ran off to do something else, came back. There's a real issue in that process. Similarly, if you look at the time that somebody entered an order and then look at the time that they wrote a note about the order and those things happened a day apart, you know that there are issues in documentation. There are ways the systems can be set up to be able to report on whether or not they're being used competently, so I think that's one level.

Then at the user level there's a whole other process where you have to train providers to get the benefit out of the system. They need to change workflows, and we need to test that competency the same way we would test it in a hospital if we were teaching somebody how to do a spinal tap. We don't just let them go into a room and do a spinal tap.

I think, Marc, your point about how potentially dangerous it can be to misuse systems has to be emphasized, and I think we have to treat the use of the system the way we treat teaching people any other kind of procedure. We teach it to them. We test their competency. We retest them. When things change we teach them the new procedures. We test those procedures. Then I think you can report on where the mistakes and errors and near misses are, but if you skip that middle step, I think all I we're going to have are tons of mistakes and near misses and bad uses of systems.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David.

David Lansky – Pacific Business Group on Health – President & CEO
Thanks. I think this is fantastic work. I really appreciate you taking us in this direction, and I have two pathways I hope you'll pursue. One is this theme we talked about among many of the comments around system nets, and obviously, we recognize that there have been patient safety issues in our healthcare system prior to the introduction of IT. Those system behaviors, we have not had a national mechanism for identifying or regulating or …. I don't know that our committee's ready to take on all the patient safety in American healthcare.

On the other hand, we probably can't get very far down this path without touching upon the partners who can help with that. The couple of allusions you've made to exploring how the Joint Commission or other bodies might be partners in this I think are really important to explore because of the dimensions of this. We can't take this on as an IT sliver of a larger set of embedded relationships so that licensures, CMS, regulatory tools, the IOM studies, Joint Commission. There are probably whole arrays of other partners who can help address the system properties within which IT is embedded.

I would think that our specific role, some of the tools that we have, one of them, of course, is meaningful use definition going forward to 2013 and beyond, and I'm thinking since David Bates came in there have been some tools in place to do for example testing of drug interactions against the IT platforms. As Neil is now suggesting, looking at ways the meaningful use criteria could evolve to have more specific

elements that assess patient safety practices and operational tools against benchmarks would be worth exploring, and so I hope you'll give us some recommendations to the meaningful use process for future criteria that might address the themes you're identifying here.

The second thing I really want to complement you on is the emphasis on patient ability to identify errors and risks. When we did work with Markle years ago surveying patients' likely interest in personal health records, by far the number one public opinion comment was it'll help me identify errors in my medical records. That was before e-Patient Dave had surfaced.

I think there's an underlying public understanding that there's a risk of error in the documentation of their own care which could in turn affect the quality of their care, and using the patient as partner in identifying errors is a really important opportunity. I hope as you think about the infrastructure to support safety work, we think more about PHRs, both the portal model and the repository platform model, like HealthVault and … and those tools where patients are beginning to access their own information as already extracted from the record. In other words, I hope we don't think about this strictly in the narrow context of EHR environment, but we think about the patient data once it's spread across the system as a tool to roll back to the source systems and identify potentials for improvement there. Thanks.

Paul Egerman – eScription – CEO
Good comments. Following up on your comment about the PHR in the patient portal, one of the things that we did do in our recommendations, though, is we just described sort of like a best practice. In other words, we didn't go as far as to say we're going to certify this which would make it required. Do you think we should've gone that far? In other words, do you think is best practice far enough, or should we be saying patient portal is required, and it has to have these capabilities?

David Lansky – Pacific Business Group on Health – President & CEO
No, I don't think we're ready to go down that path. I think the public message should be to encourage patients to look at their data and have, as you suggested, a clinician feedback system. There should be an equally easy patient feedback system. That's very hard to do, but conceptually, I think we want to encourage patients to feel like this is part of their role in healthcare is to look at and make corrections to their data partly so that'll lead to system corrections, not only to individual data corrections.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Steve.

Stephen Ondra – Department of Veterans Affairs – Senior Policy Advisor
I want to echo the thanks for the thoughtful presentation. … several lines of reporting for problems. Have you thought about how those lines come together, where they come together, and could this be made available to inform the consumer to help them make better choices?

Paul Egerman – eScription – CEO
Those are great questions. Marc? First, in terms of how the lines come together, I guess my view is that AHRQ and the patient safety organizations have already done a lot of work in that area. I'm assuming. I don't know. That's a good question if they have a way to do that because they're already bringing data together in that way.

In terms of I guess your other question about helping patients make informed decisions, that's a great question. I hadn't thought about that, but we inserted in our goal this word transparent for the information system, and I guess transparent is one of these words you always have to put into any goal statement somewhere, but we really did mean it, so this should be information that's available to consumers, to

patients, and to healthcare providers, and so that could be useful to them in making the informed decisions. Did you have some suggestions as to how we could do that?

Stephen Ondra – Department of Veterans Affairs – Senior Policy Advisor
… certainly, some sort of a transparent registry of different problems are identified so you can identify trends, also understand what are the safety issues, the usability issues so consumers are either purchasing products or utilizing products that have some …. Like when you buy a car, there are all sorts of reporting on efficiency, safety, the number of problems that occur, so something modeled on that to help inform consumers in a variety of ways that they use these systems.

Paul Egerman – eScription – CEO
That's helpful, although for the most part HIT systems are not purchased by patients. They're really purchased by hospitals and eligible providers which are really physicians. I did imagine that this reporting tool would be very useful to those groups of people.

Marc Probst – Intermountain Healthcare – CIO
Something more in the PHR for patients and the EHR world for the different provider groups because patients would want some idea of what other's opinions are of those, what problems were found, records that they may want to purchase or engage in.

Paul Egerman – eScription – CEO
Very useful, thanks.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Art.

Art Davidson – Public Health Informatics at Denver Public Health – Director
Excellent presentation, thank you. I just wanted to ask you to elaborate a little bit on one of these open questions here about the special considerations for small groups, rural hospitals, and a safety net. What did you hear during your testimony here that would make you think that there should be something different for them?

Paul Egerman – eScription – CEO
It's actually what we didn't hear. There were no reports of problems at any small physician groups or at rural hospitals. All the anecdotes, all the stories tended to be at large complex organizations, and even reviewing what I saw in the FDA database, it seemed like almost, I want to say 100%, but 98%, something well over 90% of the activity was on the inpatient side of things. In some sense that's not a surprise because where there seems to be a lot of complexity introduced is when these systems are used also for communication or you've got a large number of people involved in care.

E-Patient Dave commented that when he looked at his medical records he learned that 100 people had accessed his medical record while he was an inpatient, all with good reason. He was shocked by the numbers of people. You get 100 people, you can see why there's a lot of possibility for something to go wrong. You change that to an environment with a solo physician where you don't have 100 people involved, then arguably you might have less complexity. There may be different issues.

The answer is we didn't see anything, and so we said, well, does that mean that they should be treated in some ways differently. We don't know the answer to that yet, but that's why we asked the question.

Marc Probst – Intermountain Healthcare – CIO

I think even beyond the complexity, there's a scale factor in this. You discover a lot of these issues with your systems when there's a broad number of people or a large number of transactions that are impacting. If you have one provider that's using a particular function only occasionally, they're not as likely to discover that issue. Also, how do you aggregate all that data together to discover the issue that might be out there in those smaller environments?

Art Davidson – Public Health Informatics at Denver Public Health – Director
This might get back to the point that you're making about reporting and the urgency and the potential impact that something from the hospital may be something that they feel they need to report, but something that goes on in an outpatient area may be less likely to be reported, and we have to find a system that does better at that.

Paul Egerman – eScription – CEO
Certainly, another aspect of the question is we didn't see any reports of any issues there. Maybe it's just because they aren't being reported. It's hard to know what it all means.

David Blumenthal – Department of HHS – National Coordinator for Health IT
A couple of other questions, did you come across any information on nondisclosure agreements?

Paul Egerman – eScription – CEO
Yes, we talked about that. We actually tried hard to find information on nondisclosure agreements, and we could not find examples that they existed. We found vendors and examples where they did not exist, so we convinced ourselves in the marketplace there is a choice. You don't have to go with a situation where there's a nondisclosure agreement, but the way we looked at it was to look at the contracts, and the vendors may not be the right way of viewing it.

What we wanted to do was say, well, let's look at things from a positive standpoint. What is it that we want to see happen, and how do we make this happen? What we want to see happen is healthcare organizations report their information, vendors do alerts, and so we will just make that happen. If these things really do exist, then if people want to get the incentive money, they have to break those agreements, both the vendors and the healthcare organizations will have to do that.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Getting back to the certification process, one of the things that is different about this policy environment compared to drugs and devices in its traditional sense is that the Congress has created a voluntary, but still very pervasive certification movement if you will. It's quite likely that virtually every major system or technology that wants to be part of the meaningful use environment will seek certification. I asked before about post certification surveillance as a source of information. What do you see as the role of certification generally in improving the safety of information technology?

Paul Egerman – eScription – CEO
That's another great question. The FDA has this program called QSR which is part of their class two regulations that they do with devices that really is a vehicle to make sure that products are designed well and correct processes are in place. In our recommendations we had recommended that certification include a similar process. What I'm hopeful is that we could perhaps collaborate with the FDA in designing that, but it's a similar process to make sure that the products are designed well and the vendors have in place the right mechanisms to evaluate potential hazards and keep track of the results. There's a whole science about how to do that, and so that's what certification can and should be doing. It should be doing it as it relates to healthcare IT which is a little bit different than the device process. There are some

things to learn from what the FDA has done, but there are also some places where I think there are reasons to do some departures.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Well, we're precisely on time. It's a great discussion. We look forward to your next report in April. Thank you very much. Now, we're going to go back to the NHIN workgroup.

David Lansky – Pacific Business Group on Health – President & CEO
I don't know if Farzad will be joining us or not. Well, I'm David Lansky. Thank you very much for the chance to update you on what's going on with the NHIN workgroup, nationwide health information network to remind ourselves. The group has been busy in that we had our extended meeting yesterday, so I'm sorry I don't have more materials to share, but I think this will be primarily in the way of an update and an introduction to some work in progress that I think we'll be elaborated upon in the next month or so.

There are three topics that are on our agenda as a workgroup right now. One of them is the continuing consultation with NIST and others about the assurance framework, the levels of assurance that we think need to be in place to identity-proof and to transmit authentication credentials across the network, and I'll give you a very short update on that. Secondly, we have begun to flesh out what we are calling the trust framework, and I'll walk you through some of the components that we think will become parts of the trust framework and how we think we might use it. Thirdly, we have begun a discussion, particularly in light of the recent grants from ONC to the states to support health information exchange. We recognize that the states are busy trying to address some of the same challenges that the workgroup is addressing at the nationwide level, and we want to make sure there's effective coordination between state activity and federal activity. Those are the three topics we're on. I think what I'll do is give you a very short comment on the first and third and then just spend a couple minutes elaborating on the trust framework.

With regard to the assurance levels issue, we did in February begin a consultation with our colleagues at NIST, and the staff has been in touch with them, and they've participated in a couple of our calls to help understand how other disciplines and sectors of the government enterprise have addressed identity assurance. They've provided us with some high-level comments, and I would distill them to say we have much to think about, and the broad advice is to go deliberately. I won't say slow because I don't think slow is an operative word at ONC, but to be deliberate in developing the mechanisms for deciding at what level assurance has to be provided and what means to transmit it and how to go about certifying the infrastructure to support assurance identification.

In other words, there were no quick and glib answers coming from existing history that we could simply adopt in the existing infrastructure and turn it on to our purposes. With that advice I think our committee will continue to work with NIST and others to look at the right tools that will make sense to support the charter that ONC has. We don't have a quick answer on that topic, alas.

The second topic, the interaction with the states and the federal role, I think this was precipitated in part both because the states now have some funding to pursue HIE infrastructure and secondly because of the recent announcement of the NHIN Direct program which puts forward a set of tools, standards which will enable point-to-point direct sharing of information, what we in shorthand call push information between two parties who know each other across the network. In other words, it's a simpler subcase of the broad set of issues we want to ultimately address with connecting people to each other on the network.

That has simply created an opportunity for the state to say perhaps some of the work product coming out of NHIN Direct will be enabling of what we need to do at the state level. That is can we use the NHIN

Direct toolkit to solve, in our case, the challenges we have in California or in other locales to enable transmission of certificates or authentication credentials and so on or to identify appropriate trusted parties on the network.

The discussion's only just begun; therefore, I can't get into much detail with you today, but I think the NHIN Direct program will be underway in the next several months to produce some tools that people can use. What the workgroup will do is consult with people in the states and elsewhere about understanding what they need and how we can make sure we are enabling and not competing or diverting them from their task. I think our main takeaway is to make sure we coordinate what we do here at the ONC and policy level with what the states are needing. That'll be on our radar.

The last thing what I'll do, we have a slide in today's handout that summarizes just five high-level topics that are under discussion for the trust framework, so let me just take a minute and explain to you where we are with these elements that we're now talking about. Essentially, we've come full circle.

You may recall that we had proposed that we would talk about a trust framework in a couple months after jumped in and tackled identity assurance and authentication and directories. I think what's happened instead is we realized that these all need to weave together in a trust fabric. Ultimately, all the work we're doing around identity and authentication and transmission and secure routing and so on, all of that is to produce trust between parties on a network. Those are components of the trust fabric as a whole. Ultimately, what we need is to have every user, whether patient, professional, institutional feel confident that the information they're sharing on the network will be handled appropriately so that they continue to use the network. Obviously, our greatest fear is that something happens to jeopardize trust, and we lose participation in the network.

At the moment we're contemplating a framework, and this is brand new and we'll welcome high-level comments on this framework, but I won't get into it in detail because frankly the workgroup realized that every one of these has layers of subtlety that will need to be worked up, but at a high level, we've identified five categories of agreements and mechanisms that have to be in place to create trust across the nationwide health information network, and these obviously interact with each other.

The first we are calling a code of conduct. That is a set of mutually understood expectations, obligations, policies, rules that bind all the parties of the network to each other and give them assurance that everyone else on the network is behaving properly. The number one element on this list is law, and obviously, we have state law which varies sometimes from federal law, so we expect that any party to the network is complying with all applicable laws. In addition there may be a set of behaviors or rules that we want to expect people to ascribe to.

The second category is oversight and transparency in oversight meaning the management, maintenance, supervision, and monitoring of the trust relationship and of the exchange activities that go on. Transparency we mean both in the sense of transparency that the agreements and behaviors are transparent, but the process itself is documented and available for view as talked about in our last session.

The third category is accountability and enforcement. Once we have a monitoring system in place, we then have to enforce and provide sanctions for any breaches that occur in the trust fabric. That includes penalties if one fails to uphold their commitments as a trusted exchange partner, and again, there are many layers of enforcement possible, from contract enforcement to statutory enforcement, so it's a fairly complex domain, but we will need to address it.

The fourth category we're calling confidence in the exchange partner identities. Frankly, we're still struggling for finding the right language here, but the concept is what we often call authentication or identity assurance, how do we know that the network as a whole gives us confidence that the other parties are who they say they are and are acting in ways that their roles permit them to act? This includes perhaps maintaining and log or a record of the identities of those who are using the network.

One thing we'll come back to is whose job is it to provide these assurances. Is it the job of each party on the network, every individual doctor, user, institution, or is it the job of some intermediary layer to provide those assurances? You'll be glad to know we've introduced a new term of jargon and a new acronym to this process which I'll reveal momentarily.

The fifth category is the technical requirements for information exchange. Our expectation is that some of these elements in the trust fabric are achieved through technical standards and protocols which everyone must comply with across the network. Security is the most obvious bucket for those kinds of requirements.

Those are the five elements of the trust fabric. As I've sketched, we'll have to elaborate each of them, and then tools like authentication will fit underneath a couple of these. There's a technical aspect to authentication. There's the confidence assurance aspect to authentication. There may be an enforcement aspect to authentication, so we're structuring our thinking along these five dimensions.

The term you'll all welcome is TEO, a trust-enabling organization, TEO, and this has evolved from the old use of the word intermediary which had a hierarchical structure implication we didn't much like, so the notion of a trust-enabling organization is one which complies with these elements of the trust fabric, is in some sense accountable for its performance in these duties, and we will come to the questions of in what way is it certified or identified or given credentials that others will trust it on the network.

I think that's the summary of our work today. We just, as I said, looked at this model yesterday. We began by taking it and testing it against a couple of scenarios, for example, pushing a message from provider to another. What are the implications of these five requirements for that transaction, and then what are the signals we would need to send to the various parties about the roles they play? That work remains to be done, and we'll probably take this framework as it evolves and test it against a number of specific use cases to elaborate it more fully, but I'll stop there and see if there are questions or comments about any of the three topics.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Thank you, David. One question, I'm actually going to take the liberty of putting a question to Deven if she's still on the phone about the interaction between this trust framework and the privacy and security workgroup discussions where there have been any what you see the overlaps and implications are. Deven may have gone.

David Lansky – Pacific Business Group on Health – President & CEO
I'll mention that Deven was on some of these calls, and we did have an agreement that these, particularly obviously the code of conduct, but some of the other elements like enforcement are natural partnerships with that workgroup. I should say we've had some side conversations between people involved in the privacy and security workgroup, the NHIN workgroup, and the HIE workgroup to recognize that there are a lot of these that overlap and need to be handled in common, or at least we have to understand how each of us can contribute to a good recommendation.

David Blumenthal – Department of HHS – National Coordinator for Health IT

Mike, did you have a—

Mike Klag – Johns Hopkins Bloomberg School of Public Health – Dean
I think if the public is part of the audience for this that the use of the word privacy might be a good tact.

David Lansky – Pacific Business Group on Health – President & CEO
Very good, very wise.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Gayle.

Gayle Harrell – Florida – Former State Legislator
I like the term trust. I think going with that whole, when you start from the idea of trust, you change the whole mentality of how you're going to go about doing a national health information network. I think you need to include within that framework, number one, talking about privacy and security within that trusting relationship. That needs to be very much a part of what we are presenting to the public. The public has to have that trust, and privacy and security are part of that trust mechanism. They won't trust without it. Where do you see authorization falling within this? We've talked somewhat about authentication, but where do you see authorization in the role that the states and also the federal requirements put into what we're doing?

David Lansky – Pacific Business Group on Health – President & CEO
Authorization has come up quite a bit. Part of the issue is where authorization, we assume that authorization occurs within an enterprise, under the offices of the trust-enabling organization and that the authorization then is transmitted to the other party. Most of what we're doing here is a push relationship that is in the early stages of this activity at the NHIN workgroup level.

We've narrowed our scope to tasks where one party who already has health information is transmitting it to another party who they know for the most part in this early set of identification. They're transmitting it to another physician who's providing care to a pharmacy who's dispensing medication to a patient who has received the care and has a known identity and address. We have not even really looked at the issue of directory services to identify not-known parties and their location. To the extent we've narrowed our scope, authorization has been a less acute issue for us than it will be when we look at the other use cases, but it's on our list of topics.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Other questions? This is making concrete something that is still very much in evolution. I expect we'll be hearing other acronyms as this process goes forward. We have maybe an acronym-producing machine here, this workgroup, the policy committee, but I think that having isolated the core functionalities, if you will, for trust is an important step forward. Working with the states to see what their role is in facilitating the development of this trust framework I think might also give them important direction for how they can use the grant awards that they've received.

David Lansky – Pacific Business Group on Health – President & CEO
I would say that all three of the workgroups I mentioned who've had some discussion about this realize that the state role is very significant in each of those three workgroups, and there's a cross-cutting theme. We need some way of continuing that conversation so the states get a consistent signal from our discussions, and we in turn learn from them what we really need to address.

David Blumenthal – Department of HHS – National Coordinator for Health IT

Since I have my CMS colleague to the left, the Medicaid program also plays a really critical role in making it possible for all these goals to be realized. Any other questions, comments? If not, we'll thank David for his comments, and we're running ahead of schedule, but I saw that Jamie is here, and I don't know if the Johns are on the phone at this point. Janet I see is here.

Judy Sparrow – ONC
… John Halamka to dial in or if they want to go ahead and—

David Blumenthal – Department of HHS – National Coordinator for Health IT
Should we do our report on the certification process first and then—

Judy Sparrow – ONC
As long as we can begin right at 11:00 for John Halamka. He's between presentations, so it's important that he comes on at 11:00.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Why don't we, is Steve Posnack here? I saw Carol. Okay, great, why don't we have Carol and Steve come up and just report on the regulation, and then if necessary, if we're not done in time, we can interrupt that, go back to the report of the standards committee, and then resume.

Steven Posnack – ONC – Policy Analyst
We were in the back preparing. My name is Steven Posnack. I work in the Office of the National Coordinator. I'm joined by Carol Bean also from the Office of the National Coordinator. We'll do our quick introduction first. I work in the Office of Policy and Planning. It's a privilege to present to you today, long time listener, first time presenter, all the way back to the AHIC, so the Webcasts are always great. Along with my other responsibilities, I serve as ONC's lead for regulatory affairs, including regulation development which is why I'm in front of you today with Carol.

Carol Bean – ONC – HHS
I'm Carol Bean. I'm in the Office of Standards and Interoperability and currently the lead for all of ONC's activities in testing and certification programs, and Steve once referred to me as the other half of his brain. I've had a lot of support roles for Steve and the reg writers for the NPRM itself.

Steven Posnack – ONC – Policy Analyst
Great, well, we will just charge along. I've mastered the remote already, first click. The first slide that I have here for you today is now that we've published all of the regulations that we need to publish related to meaningful use and standards and certification criteria and the certification program, the question comes up can we look at them globally and say how does all this work. The policy architecture required to implement meaningful use is comprised of three interdependent rule-making, and I've used this slide to illustrate how all these rule-makings work together.

The first test to do and how someone becomes a meaningful user of certified EHR technology, there's the key phrase. The first regulation underneath the term meaningful user relates to the meaningful use regulations which specify objectives and measures, the behaviors that eligible professionals and eligible hospitals will need to meet in order to get their incentive payments. That regulation is correlated with the Interim Final Rule on standards and certification criteria which we released at the same time and published on January 13, which specifies certification criteria and the underlying standards in those certification criteria that, according to two terms that we define in the regulation, what complete EHRs and EHR modules would need to include in order to support a meaningful user's attempt to achieve meaningful use, stage one at this point.

Then the third and final interdependent regulation that we just published relates to the certification program, how these complete EHRs and EHR modules get certified to provide assurances to eligible professionals and eligible hospitals that adopt them so they're going to have the technology capabilities that they need to become meaningful users. That's where the third graphic fits in where we've, and I'll get into this in a little bit more specificity as well as Carol.

As David alluded to earlier, we are an acronym factory, so we have two new acronyms for folks to learn, the first being an ONC authorized testing and certification body. That's an ONC ATCB, and an ONC authorized certification body which is an ONC ACB, and we'll go into more detail about what each of those bodies will be and what their roles will be.

Using the certification criteria and standards, either of these two bodies will test and certify complete EHRs and EHR modules, and they will bubble up and become either a certified complete EHR or, as we specified in the Interim Final Rule, a combination of certified EHR modules would also meet the definition of certified EHR technology. Circling back, this is who all the rules work together. This is what the framework will be going forward, and how we'll continue on.

Just a quick recap of the statutory authority that we're using to implement the certification program's rule, it's important to note that this authority was granted to the National Coordinator, so we need to implement that, and regulatory processes are one way to do it. I've heard a number of questions asking why we've had to go through rule-making, and just to provide some context, I just wanted to give a couple points for people to take note of. We go through rule-making when we need to impose obligations on the private sector or if we're providing legal benefit or granting legal right to certain entities in the private sector. There are many other factors that are also involved. I don't want to say that those are the only two, but just to get a sense of why we have to go through the regulatory process, this is one where we are both imposing obligations and granting legal rights in order to implement the National Coordinator's authority.

Back to the recommendations that we received from you all a while ago, you recommended that we focus certification on meaningful use, check. I believe you can see that we've been moving forward in that direction. We've been listening to that, also, leveraging the certification process to improve progress on privacy and security interoperability, again, a foremost recommendation that we've embodied in all our regulatory processes.

Improving objectivity and transparency of the certification process, I think some of the things that Carol will go through will also help to explain how we're making strides in this regard. I would say that it's going to be an incremental process, that we're going to build in more objectivity and transparency as the programs move on, and you'll see, pending what we've proposed, how we believe we can build in more objectivity and transparency. Expanding certification to include a range of software sources, again, we really took that recommendation to heart, and we believe that our program and our proposals are as inclusive as possible. To develop a short-term certification transition plan, we've proposed both a temporary certification program and a permanent certification program, so we believe our proposals fit within that paradigm.

Playing off the quick authority lesson that I gave you a couple slides ago, there are two programmatic purposes for our Notice of Proposed Rule Making on a certification program. The first is to establish a process for the National Coordinator to authorize organizations to perform health information technology testing, at least in a temporary certification program and certification in the permanent certification program. Again, this gets to implementing the authority that the National Coordinator has to confer, some of the National Coordinator's legal rights and benefits that Dr. Blumenthal was granted to provide to these

organizations that we authorize, and it also specifies how complete EHRs and EHR modules would be tested. This picks up on some of the issues and topics that we teed up in the Interim Final Rule, so hopefully, the proposed rule will answer some of the questions that people had after reading the Interim Final Rule and standards and certification criteria.

This slide is a little bit busy, but it lays out our rule-making approach. As I alluded to, we are proposing in one Notice of Proposed Rule Making two different certification programs. We intend to finalize these two rule-makings in two separate final rules, and that will allow us to expedite the temporary certification program. As I've laid out here in a couple of bullets, we intend to have it be operational for meaningful use stage one, and we anticipate publishing a final rule for this temporary certification program synchronously with the final rules for meaningful use and the standards and certification criteria final rule which we can joke around its double-final, or its final-final of the Interim Final Rule, so there'll be a lot of rule-making going on after I go back to the office today. Then the permanent certification program we expect to be operational sometime before meaningful use stage two would begin. It would pick up the reign, and we anticipate issuing that final rule sometime later this fall or in the fall time period.

Important to note there are two separate comment periods. Due to the expedited nature of needing to get this temporary certification program turned around, we've asked for a 30-day public comment period. The rule is up there on regulations.gov. Don't wait. That would be my advice. As soon as you can get your comments in, that will help us start to go through and reconcile and organize those comments.

I didn't get to tell you something, but I'm going to stay up here with you when you do your session to give a little brief on our IFR comment processes as well. Then we've allowed for 60 days of public comment on the permanent certification program proposals. We are going to take in all the timely comments on the temporary certification program up to day 30, and anything that comes in afterwards, we will use all those comments received from day 1 to day 60 to inform our rule-making for the permanent certification program, so no comments will be lost, and we'll use them to build on our permanent certification program's final rule. I don't want to take up too much time, but I guess I'm dancing as well for Dr. Halamka to get on the phone.

Just core elements of the temporary and permanent certification programs, they both include an open application process. If there's an organization out there that believes it's qualified and can meet the proposals that we've made in the temporary certification program or the permanent certification program, they can submit an application to us, and we go through the procedures, which I won't bore you with. Organizations would be authorized to perform the testing and certification of complete EHRs and EHR modules or both in the temporary certification program, which is why I have testing in brackets.

In the permanent certification program, our authorization focus is solely on certification. This again is one of those transitional factors that we've built in our proposal. There could be an organization that gets authorized to certify complete EHRs which are all-in-one basically out of the box conceptually as we've defined them or EHR modules. An organization could request authorization to test and certify an electronic prescribing module or some other smaller component that we've proposed related to certification criteria. We believe that this will hopefully span the number of people out there that could perform certification and help prevent bottlenecks and other types of situations.

The third note that I have down here as well that's specific to the permanent certification program and what we believe will help improve objectivity and transparency in the permanent certification program has to do with the accreditation requirements that we've proposed. In this we've gone into great detail to explain conceptually the differences in competency that we believe exist with testing complete EHRs ad

EHR modules and certifying complete EHRs and EHR modules and that there are separate competencies for those and that each of those competencies should be separately accredited.

In the permanent certification program, the National Coordinator would approve an accreditor for the certification competencies, and we propose that we would work with NIST through the National Voluntary Laboratory Accreditation Program, probably another new acronym for some folks, and they would accredit the testing laboratories of complete EHRs and EHR modules. I know that there may have been some articles or other information out there that we'd be accrediting testing labs like diagnostic testing labs. That's not the case. We have a little bit of terminology overload, but rest assured that we're talking about laboratories that would test and certify complete EHRs and EHR modules and other health information technology going into the future.

Final note (and I think this is my last slide before I turn over to Carol) would be that we've specified particular authorized methods that these bodies would perform for testing and certification. This is a little bit of a column A, column B type of routine. The primary method which is required is that they be able to test and certify complete EHRs at their facility, so you would bring it the authorized testing and certification body. You would present it to them, and they would put it through its paces.

We've also proposed a number of secondary methods that we believe will help others out in the industry. This includes at the site where a potential vendor has developed their EHR technology, at the site where the EHR or EHR module resides, and ONC ATCBs could offer to go physically to an eligible hospital's location and test and certify the EHR module kind of in vivo, and we've also proposed that they may have the capacity to test and certify complete EHR and EHR modules remotely. This may be something that's a little bit forward-looking, but we believe that this will have benefits in the future as the technical capabilities are improved. I'm going to turn it over to Carol.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Carol, let's do a time check here. It's 11:00, and if—

Judy Sparrow – ONC
Not on yet.

John Halamka – Harvard Medical School – Chief Information Officer
I'm John Halamka. I'm here.

David Blumenthal – Department of HHS – National Coordinator for Health IT
John, how much time do you have?

John Halamka – Harvard Medical School – Chief Information Officer
I can certainly go late until 12:30 if you need to continue on your agenda as is.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Great, so I think we'll be another 15 minutes or so. Could you wait that long?

John Halamka – Harvard Medical School – Chief Information Officer
That's totally fine.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Okay, Carol, go ahead.

Carol Bean – ONC – HHS

I get to describe the pictures. Pictures being worth a thousand words I hope I don't do a thousand words per picture. I don't intend to because there are four pictures, and I would just orient you to the four slides. The first two slides focus on the proposed certification program, the first temporary and the second permanent from a very high level and the primary organizations and stakeholders that are involved. The second two slides show how products and technologies would be certified under the two programs, and they're essentially overlaid on these first two slides that are depicted first.

We'd like to remind you of the basis of the design of these programs, or first, under the assumption that the separation of the development of the criteria and technical requirements from the certification process itself would be a good thing. We want to keep the foxes out of the henhouse. Two, this is based very heavily, as Steve noted, on the recommendations of this committee and the certification adoption working group which received a large amount of public input and second in close consultation with NIST, the National Institute of Standards and Technology, which was very instrumental in helping educate us and ensure that the processes that we've proposed met international standards and best practice for conformance assessment that are widely used in many other industries.

This first slide here is a high-level view of the temporary certification program, and I would ask you to note that it is very similar in design to the previous program that we have used for the past few years. In essence, that's having one body authorized by the Office of the National Coordinator to do both testing and certification.

The things that I would draw your attention to that are somewhat different are that in consultation with NIST, NIST will be helping us, and they've helped us to design the evaluation criteria for the testing and certification bodies, but also NIST is developing as we speak the test method for the technical requirements, and that's the standards and certification criteria. The test methods are being published publicly on the NIST Web site. Now, they've got one wave up, went up March 1. The next wave will go up this week, and then there'll be two subsequent waves. The test methods are essentially the protocols and procedures, the data, and the testing tools that would be used by the test labs to develop the test scripts that would be used to test the products and technologies. That's the primary take home that I would like you to see from this particular slide.

The next slide shows the permanent certification program in a similar format. Here it shows the key features of the last one in a very similar way. The difference is that I would like to draw your attention to our, as Steve noted, the formal accreditation process for both testing and certification and the fact that we have a formal separation between testing and certification. A single organization could do both testing and certification, but there are all kinds of requirements for the separation of those processes within that organization if they choose to do that. As I said, it's very similar to the temporary program. This is intentional so that the temporary program serves as a logical precursor for that.

Now, looking back at the temporary program slide, this is we've overlaid the process under which a product or technology would actually be certified by a vendor who's proposing this or an eligible hospital that's got something already installed in their system and would note the sequence there would be that they would submit their EHR, their complete EHR or EHR module or request that the testing lab come in to their facility to test them. It would be tested. They would receive a test report. The test report would be sent back directly to the applicant itself, not forwarded onto the certification body until they feel that they are ready to apply for certification. This allows for any kind of correction or remediation that may need to be done, allows them to choose the timing for their certification to the testing body itself which here is in the same beast.

I will go ahead now and go to the next permanent certification. These steps are the same in both, but for fun and to perhaps challenge more of your brain cells, this overlays it on top of the slightly more complex permanent certification program, but here shows that, again, the submission for testing, the test report, and the application for certification would go on exactly the same in both processes.

Now, the certification bodies, we anticipate that there will be multiple certification bodies, would submit reports on the products that they have certified to the ONC because all they can discuss is what they have actually certified themselves. We have proposed in the NPRM that we maintain a master certified HIT product list, and that would be the aggregate of all of the products and technologies that have been certified, specific information as to details in the NPRM about those products and the folks who have either produced them or are bearing the certification itself.

Then that certified product list would be available to the public on the ONC Web site so that anyone could come in, a potential purchase could come in and say is everything I've got, is it in the aggregate form certified EHR technology, or what do I need to get? I've got these pieces. How do I need to combine? It's essentially intended to address the needs of any kind of purchaser or a holder of the certified technology program. It would also provide the information that we would be able to share with CMS, and that's a separate discussion, but it would form the basis for the kinds of allegations that they would need to do. That is at a very high and quick level a description of the processes, the temporary and certification programs that we have proposed in the NPRM.

David Blumenthal – Department of HHS – National Coordinator for Health IT
I'd like to just make one clarification. Carol said that the temporary process would be very much like the current process of recognizing the single body that was recognized to certify technologies, HIT, but there will be a competitive open competition, and we actually know that one other organization has expressed interest in becoming a certifier.

Carol Bean – ONC – HHS
Thank you for that clarification. If I misled, yes, it is intended that there would be multiple and that any organization that wants to, but the process itself would be similar, but who is doing that is going to be available to any and all-comers who feel that they can satisfy the requirements and that who then do meet the requirements for that. Thank you.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Sure. David.

David Lansky – Pacific Business Group on Health – President & CEO
In permanent certification do you plan to place any limit on a number of bodies that might be certifying? In having participated in the work of the group that did certification initially, they relied a tremendous amount on volunteers from community, and I'm just concerned about how economics will work if there are too many certifying groups.

Steven Posnack – ONC – Policy Analyst
I think under prior processes a lot of volunteers were used to help develop criteria, and that was a large man and woman hours devoted time. The HITECH Act changed how that happens in the standards committee, your colleagues in the other side of the FACA isle are responsible for recommending standards implementation specifications and certification criteria to the National Coordinator for the secretary to adopt. There's a little bit more a top-down approach and a single source of certification criteria now so that any one body that could potentially be authorized under the current program would all

use the same certification criteria. The development or generation of those criteria wouldn't be distributed across all those organizations. I don't know if that completely addresses your question.

Carol Bean – ONC – HHS
Part two of that would be, yes, we anticipate that there would be multiple, and we do not anticipate putting any limit. I think there will be a natural limit on the organizations that are qualified to do this, and my expectation would be that they would not be using volunteers, that they would have staff that would perform those functions.

David Lansky – Pacific Business Group on Health – President & CEO
I've largely just been concerned that there will be a sort of a race to the bottom with multiple entities doing this and whoever puts things out at the lowest price—

Carol Bean – ONC – HHS
I think the race to the bottom in terms of cost may be true, and I think that would not necessarily be a bad thing if we are able to affect a lower cost, but all of the certification bodies, all of the testing labs would have to use, and this is something that we've done is pulled out the requirements which are international standards for the way that they have to process these things, and as Steve said, all of the requirements will be the same regardless of who does the testing. The requirements will be the same regardless of who does the certification. We set those, so within that they can't race any farther below what we are able to establish and intend to establish as the necessary criteria. Now, some may have higher, and that may be a way that they set themselves off in the market, but I do imagine that costs will be lower as a result of a commoditization of this process.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Paul.

Paul Egerman – eScription – CEO
First, I just want to say, Carol and Steve, this is excellent work. The NPRM, it's great. It's fantastic work. The feedback I've gotten so far from the industry is this is exactly what we were hoping for, and the people were a little concerned that it was a little bit of a wait to get here, but I guess the best things in life are worth waiting for, so we're very pleased with this.

I actually have an administrative question. Maybe Paul Tang can answer this. The certification workgroup will want to make a comment on the temporary program; however, the comment period, if I understand right, ends April 8, which we don't have a meeting between now and April 8. The question I have is for us to make a comment do we need to establish a phone meeting of the policy committee, or should the workgroup just submit its comments directly to ONC and skip that part. How do you want to handle that?

David Blumenthal – Department of HHS – National Coordinator for Health IT
You're going to test my knowledge of the Administrative Procedure Act. Where is Jodi Daniel when we need her? Is she over here? Steve.

Paul Egerman – eScription – CEO
This is more I think a FACA administrative question.

David Blumenthal – Department of HHS – National Coordinator for Health IT
It's really.

Paul Egerman – eScription – CEO
Does the policy committee need to approve the workgroup's comment?

Steven Posnack – ONC – Policy Analyst
Yes, I think if you wanted to pursue that we could probably talk with Judy. You'd probably have to have a brief phone amongst the members of the entire committee so that you could take that recommendation as your own and pass that on because the full committee needs to make recommendations to the National Coordinator,

David Blumenthal – Department of HHS – National Coordinator for Health IT
We might be also able to do it by email I would think. I don't know. Is that true?

Steven Posnack – ONC – Policy Analyst
The public element would be something that we would need to take into account.

David Blumenthal – Department of HHS – National Coordinator for Health IT
We can use an NHIN Direct.

Steven Posnack – ONC – Policy Analyst
The 30-day comment period is April 9 just in case you gave anyone a heart attack. They get one more day. It's coming up quick, though, so like I said, make sure you get your comments in. Thanks a lot.

David Blumenthal – Department of HHS – National Coordinator for Health IT
David, do you have a comment?

David Lansky – Pacific Business Group on Health – President & CEO
Yes, just a question I guess about the structure. I like the structure, and I think it's a very good step forward. You've taken into account a lot of the feedback. There's always a balance if you talk about the private sector versus public sector role in this and allowing for nimbleness and evolution of the standards so that the industry can move fairly quickly into new opportunities. How will this structure accommodate fast-moving changes in the technology and the associated standards? Is it a matter of waiting for the standards committee to speak, or will NIST through the yellow technical requirements box, the gold box, is that a vehicle for fast accommodation to changes in the environment, and how do we avoid having this be too rigid of a structure to inhibit evolution?

Steven Posnack – ONC – Policy Analyst
This may be more of a response related to the Interim Final Rule that we just published on the standards and certification criteria. Some of the rate-limiting steps are going to be where meaningful use is going, so in keeping locked up with the different stage requirements. We discussed in the Notice of Proposed Rule Making for the certification program how we would treat some of the "minimum standards" that we identified in the Interim Final Rule. Not only is there a kind of interdependency between all three rules, but there's also an internal interdependency between these two rules and how they interact and how the bodies themselves use the certification criteria and standards that we've adopted.

We're going to be going back and looking through all the great public comments that we just received on the Interim Final Rule in trying to figure out a way to both balance what certification will provide a snapshot of a complete EHR or EHR modules' capabilities at that point in time versus where the industry is going if new standards come out, if new code sets come out, how we can make it a little bit more flexible and nimble that folks can either voluntarily adopt them and not invalidate their certification or get a

subsequent certification to a new version of standards. There are a lot of complexities in trying to pursue that, but we want to move forward.

David Blumenthal – Department of HHS – National Coordinator for Health IT
It's an excellent question, David, and I think the issue is where is the time-lag going to be greatest. My guess would be that the time-lag to recognizing changes in standards, and certification criteria would be greater than the time-lag to incorporate those revised standards and certification criteria into the certification process. That process, the gold box up there where it says technical requirements could move a lot faster than the regulatory process, and Steve is right in bringing us back to look at how the rule-making which we are required to do on standards and certification can be made as nimble as possible. Any other comments? If not, thank you, Carol and Steve. They've done this presentation before, and every time it's a little different and a little better.

Steven Posnack – ONC – Policy Analyst
Keep you on your toes.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Speaking of IFR, now we're going to take comments from the standards committee. We're going to have Janet Corrigan and Jamie Ferguson and Floyd Eisenberg here as well, and we're going to have John Halamka on the phone. I don't know if the other John is on the phone.

Jonathan Perlin – Hospital Corporation of America – CMO & President
This is John Perlin. I have rejoined.

David Blumenthal – Department of HHS – National Coordinator for Health IT
Great, the two Johns and Dixie.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
I'm here. This is Dixie.

John Halamka – Harvard Medical School – Chief Information Officer
Jon Perlin, did you say you were there?

David Blumenthal – Department of HHS – National Coordinator for Health IT
He's not, okay.

John Halamka – Harvard Medical School – Chief Information Officer
No problem. Well, let me kick us off because I know Janet does have a hard stop at 11:30. Thank you very much for the opportunity to present the HIT standards committee progress report and really kick off the notion of how we are yin and yang with you. That is we very much seek your guidance, want to be in lockstep with everything that you're doing and want to be as helpful as we can as the policy committee who decides on what are the next 2013 and '15 priorities and how there can be technical standards and certification criteria in support of everything you're doing.

Our structure, just to move to the first slide is that we have four workgroups. Jamie Ferguson oversees the clinical operations workgroup. Janet Corrigan with Floyd's able help oversees the clinical quality workgroup. Dixie Baker is the … oversee privacy and security. Aneesh Chopra here is implementation. What I'd like to do is turn it directly over to Janet so that she can present her material, and then we'll come back and I will tell you a bit about generally what our priorities are and turn it over to the other workgroup chairs for their reports. Janet, please go ahead.

Janet Corrigan – National Quality Forum – President & CEO

Thank you, John, and thanks to my colleagues for letting me go first. I have another commitment across town that I have to sneak out to pretty quickly here. Floyd's going to join me, and first I'm going to address a few of the broader issues related to the 2011 meaningful use measures and 2013 measures as well, and then Floyd's going to address some very specific issues about the vocabulary and HIT standardization requirements to support the 2011 measures.

By way of an update or background, efforts are currently underway to do the retooling of about 110 measures, virtually all of the measures which are in the NPRM that have been identified. They are not knowing which ones are going to eventually be used for meaningful use at the end of the process. We're working very actively, NQF is, wearing my NQF hat for a minute, with the various measure stewards on those retooling efforts and expect that the measures will have eSpecifications. That work will be completed by the end of September or thereabouts.

There's one issue that hasn't been addressed, and that is currently we do not have a test deck or a test bed in place to actually run the eSpecifications for the various measures to see whether or not they accomplish what they're intended to accomplish, and that's something that probably should be addressed sooner rather than later.

The second issue that we've come to understand is that as a result of this initial retooling effort we will begin to identify value sets. The retooling effort is currently building off of the quality data set which was identified by the health information technology expert panel that Paul chaired for us and others here participated in. The various measures are using the data types that have been identified in the quality data sets.

One of the things that we're beginning to realize is that we will need to build value sets that will then support the specification of all the many quality measures. For example, if you have a measure that is looking to see whether or not aspirin was administered to a hospitalized patient, you need to identify the Rx norm codes that apply to enteric-coated aspirin as well as plain aspirin, and you need to identify the appropriate codes and information to be able to know where to access in the record whether or not the aspirin was administered to the patient. That's sort of is a value set that can then be used by many different measures and also can be used for other secondary uses, such as public health reporting, probably comparative effectiveness, and on and on, and as well as being important for clinical decision support. Out of this initial retooling effort, there will be the identification of sort of I guess you'd almost call them starter value sets, but this is an issue that will need to be addressed on a broader scale going forward by the policy and standards committee.

The other thing that the clinical quality workgroup is sort of awaiting and anxiously awaiting some more direction from the policy committee as to the types of measures that you want to focus on for 2013 and 2015, and I just wanted to flag that there is a time issue here. For the 2011 meaningful use, I think we pretty much took advantage of all the low-hanging fruit in terms of existing performance measures that are well specified have been evaluated and vetted. For 2013, especially if the desire of the policy committee is to begin to address some of those aspects of performance that we haven't been able to address to date because we didn't have electronic health records with connectivity, so we really couldn't address things like care coordination to any degree, if it is your desire to move aggressively in those directions for 2013 and 2015 (and I know it is), work will need to begin immediately because the pipeline and timeline for measure development and testing is at least eight months if not upwards of two years. I just wanted to flag that timing issue for you.

One other thing to consider is that for 2013 it may be that it would be wise to lay some groundwork now and to do some outreach to leading systems out there that have electronic health record systems in place and probably have developed performance measures that take advantage of the capability and what you can do with those systems. That may be a fruitful area to begin to explore because we could potentially bring in measures that at least partially or are almost fully developed for consideration and use at the national level. Now, I'll turn it over to Floyd who's going to speak to some of the detailed issues of HIT standards for the 2011 measures.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
Thank you, Janet. What I will speak to is, what you'll see is very close harmonization with what you'll be hearing from Jamie on the clinical operations workgroup. The first comment on the IFR in terms of identifying allergies, there is discussion in the IFR about using UNII codes I believe in the second year, but in the future not at the beginning. Two issues for managing quality measurement, we have to know allergies, so that needs to be done sooner for measurement. We also understand the value of having the component level allergy identified, but most EHRs today if they identify allergies related, and they do, it's related to the drug level, not the component level. UNII takes us to the component level. While there is benefit in that, we're not certain how fast that can happen.

The second is in vital signs. There is no identified terminology in the 2011 timeframe, and they are needed for some of the near-term quality measures, specifically blood pressure, body mass index (BMI), and so I know the operations group is speaking to LOINC and SNOMED. Having a single vocabulary standard would be beneficial for the quality side. We were suggesting LOINC there.

On the units of measure vocabulary, UCUM, units of measure also are important for identifying the appropriate data for quality measurement, and in 2011 it wasn't clear what would be used. Those are three fairly straightforward questions.

On CCR versus CCD, the team did agree that there is benefit for interoperability sharing summaries. Most of the quality data work is based on very discrete data level definitions identified within the CDA architecture of which CCD is one example, so CCD was felt to be more beneficial for quality measurement at this point.

As far as the reporting out, there was no disagreement with the PQRI XML except that the use of it primarily is in the ambulatory community for reporting. Hospitals are not currently using that today, and the question is would that provide an extra burden to hospitals to move to a new method for reporting, say, for hospital compare from what they do today if there may be something in the future that is different. That's one comment. We do agree that QRDA is not ready at this point for quality reporting, but a CDA-based model makes sense.

Janet Corrigan – National Quality Forum – President & CEO
That's essentially the clinical quality workgroup report.

John Halamka – Harvard Medical School – Chief Information Officer
Great. Well, thanks very much to the two of you on this tight timeframe. Just generally what the theme of today will be is we wanted to show you what our hot issues are, what our teams are working on, what we see as our future work, and then after our committee reports, what we'll ask you is what do you see as some of those areas where we could be most helpful because we know that over the last year we have been moving at an incredibly rapid pace. I think that we have worked very, very well together, but as Janet and Floyd have outlined, it's important to actually know where the puck is going to be because there will be some lead time. Sometimes they will need new standards, gaps that need to be closed,

definitions that will take time, and consensus processes to build, so we want to make sure that we are working very closely together. For our next report, let me turn it over to Jamie to describe the hot issues in the clinical operations area as well as his comments on the Interim Final Rule.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thanks, John. Just generally to refresh the overview of the clinical operations workgroup, we have responsibility for making standards recommendations and certification criteria for the content exchange standards and the vocabulary standards that are used, essentially the package that's sent between entities for meaningful use. I'm going to focus first of the item here, vocabulary taskforce. This is where we've started holding a series of hearings on the needs for controlled vocabularies for meaningful use.

We're starting with governance and essentially rules of road for how the value sets and subsets, updates, and so forth should be handled and processed with respect to the controlled vocabularies that are needed. Then we plan to move on into the infrastructure and tooling and examine what infrastructure, what tooling we would want to recommend for meaningful use. Then we'll approach the area of coordination between the different stakeholders that need to be involved in the controlled vocabularies.

We did hold our first hearing last month. We actually have our second hearing next week. Some of the key messages from the first hearing which included panels of EHR vendors, vocabulary service providers, and the messaging standards organizations, some of those messages were that there's a need for a centralized process and a centralized repository for the value sets that Janet and Floyd are talking about, but also for the start sets, the subsets, perhaps frequency-based subsets of the required vocabulary standards to give EHR implementers a starting point so they know which terms and concepts they need to start with. There was a strong agreement on the need for using private sector, particularly standards development organizations to develop these value sets and a need for mechanism to coordinate value sets across multiple different use cases, so it's just a preview, perhaps, of the coming report that I would hope to give in the future after we have more of these discussions on the vocabulary area.

I do want to go into our comments on the Interim Final Rule. The primary theme here is that we need to balance and enable conflicting requirements for both flexibility and specificity in the content exchange and vocabulary standards. We felt that flexibility is needed both for innovation and advancement to occur, but at the same time, specificity at a very detailed level is absolutely required to achieve interoperability between any two eligible professional offices or hospitals.

Frankly, we felt that the IFR got this balance exactly wrong, and we have recommended an alternative mechanism to meet these different requirements simultaneously. Generally, what that involves is a recommendation to move to a higher level or a less specific level if you will of the adopted standards for content exchange. As an example where the IFR adopts HL7 v2.5.1 for particular purposes, we would recommend adopting v2 period and then enabling interoperability specifications that would give a particular dot release version of the standard as well as a particular implementation guidance with full specificity through alternative mechanisms outside of the rule-making process. That could potentially be done through guidance letters, through alternative processes involving NIST and the testing process, through certification, and through other mechanisms. The way the IFR is constructed now, however, specifying in this example HL7 2.5.1 with no implementation guidance still leaves literally hundreds of different optional fields that can be implemented and will be implemented in various ways, essentially ensuring a lack of interoperability between entities, so this is our proposed remedy to that issue, and this is essentially our new approach since we had previously recommended the full specificity should be in the IFR.

Just briefly to touch on those things, we're recommending a clinical document architecture of HL7 in addition to the CCR would be the standard for patient summaries, NCPDP script for medication transactions, the standard HIPAA transactions, the X12 4010A1 and X12 5010 for the administrative transactions. For quality reporting, actually, the slide has a typo. We recommended both XML and the clinical document architecture should be adopted, so the XML Web protocol standard then would be used. For example, where PQRI is the implementation specification, XML would be the standard, but for the alternative quality reporting mechanisms that Janet and Floyd were mentioning, the HL7 clinical document architecture would be the standard.

We're also recommending implementation guide floors, a particular version having a specific implementation guide that removes all that optionality from the base standards is not necessarily a bad thing and could even be in the regulation that there's the ability generally for software packages to accommodate multiple such implementation guides. Vendors frequently accommodate multiple different implementations at the same time, so it didn't seem to be an undue burden to have at least a floor of a fully specific implementation guide for interoperability purposes.

I think we've already heard about the need for the vocabulary starter sets. We added recommendations for some of the required cross maps between the vocabularies where mapping is needed, and in vital signs as Floyd said, we also recommended that there should be an adopted vocabulary, although we recommend both SNOMED CT and LOINC should be adopted for that purpose. In general we find that EHR implementers who use SNOMED for problem list purposes also use it for vital signs. Although it would be slightly more convenient for the measure developer community to have only one code set to deal with for that, we didn't feel that their convenience should actually drive clinical documentation practice.

Finally, we requested in our comment letter clarification on the scope of interoperability in terms of where should these standards apply. We wanted a definitive statement that the standards would apply to essentially interoperability of content exchange outside the boundaries of closed systems, so essentially between entities.

John Halamka – Harvard Medical School – Chief Information Officer
Thanks very much, Jamie, and you've highlighted the issue that David Lansky raised perfectly which is how do we provide enough guidance so that we have interoperability, but not too much guidance so that we quash or slow innovation in any way. Hence our proposal which is I think we can all generally agree on broad families of standards, HL7 v2 as a family, and then a starter or a floor, but then outside of regulation (to the extent that Jodi Daniel tells us this is okay) that there could be additional guidance, of course, appropriate processes through the standard and policy committee's advice to ONC to result in such guidance, but then we would hopefully have a very nimble system that allows new implementation guidance to be issued as the industry is ready to receive it.

Getting rid of optionality is very important as Jamie has highlighted. Saying HL7 2.5.1 is a bit like saying take transportation between New York and Dallas. Well, is that a train, a plane, a car? They all work. We want to actually make sure there's enough guidance so that a vendor can implement a system that is as close to plug-and-play for the small practice especially because my experience in implementing small practices has been they have to pay $5,000-10,000 for every lab interface. They have to build compendiums of lab ordering vocabularies from scratch. It is anything but plug-and-play. Jamie, anything you'd add to that?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think that's a great summary.

David Blumenthal – Department of HHS – National Coordinator for Health IT
John, Jodi Daniel is a very wise observer of the Administrative Procedure Act, but we probably will have to get our general counsel's office to give us advice about this particular topic because the question of what has to be within a rule and what can be done without a rule is way above our pay grade, but it's a very interesting proposal and certainly would be more nimble if it were feasible, but we don't know if it will be considered feasible by our council.

John Halamka – Harvard Medical School – Chief Information Officer
Very good, well, we will seek your guidance. The last thing we want to do is ossify in regulation a standard that will by industry and by EHR, clinician and user inherently change, so it's this tension of specificity and nimbleness, and we hope that this proposal meets with the approval of the policy committee, ONC, and your legal council.

Let me move on then to privacy and security. We know that privacy and security is foundational to everything that we do, and just as Jamie described the clinical operations workgroup as vocabularies and content, privacy and security includes the transmission and all aspects of the technical security to ensure that as data goes from place to place, it is not changed, only the right people see it. The data has non-reputability, and so Dixie is going to present her hot areas as well as several comments on the IFR.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Thank you, John. Our first bullet here just lists a number of topics that as we address in privacy and security like authentication, access control, auditing, and I would also like to comment that these areas help protect not only patient privacy, but also address the very important area that we discussed earlier this morning of quality of care and patient safety.

As Jamie mentioned, the emphasis here is really on information exchange, but in the security area we also are looking at internal trust mechanisms that exchanges depend upon. For example, the authentication of people and entities that are involved in an exchange between organizations, that authentication is done within an organization so we can't just look at the intersection between organizations, but also in some cases, identity being one of them, we really need to look within the organization. We look at technology standards, and we're specifying or recommending technology standards and certification criteria to support privacy and security policy and, as I said, as well as safety and quality.

Our priority of the areas that we look at are aligned and driven by the privacy and security policy workgroup that Deven McGraw is leading, and I serve on her workgroup which is really helping to make sure that we are aligned with the policy coming out of your committee is what aligns with what we're doing on the standard slide of things. A good example of that is that I know that the privacy and security policy workgroup has identified as a high priority consent management because the standards around the management of consent and exchanging consents between organizations are all in development. None of them are mature. I've launched an effort to really, a series of education sessions that will allow our workgroup to come up to speed on what's really being done by HL7, for example, by OASIS, by integrating the healthcare enterprise, what's being done in the standards development organizations that relates to the management of consent.

Next slide please. I have two slides about the IFR. We had a number of comments about the Interim Final Rule. The certification program as was addressed before includes the certification of EHR modules as well as complete EHRs, and we certainly agree with this idea that we certify not only complete EHRs,

but EHR modules. We think that that's essential, but it does present some challenges with respect to enterprise-wide privacy and security.

For example, if we require that each module submitted for certification meets all of the security certification criteria, the result would be very disjointed privacy and security implementation across an enterprise. On the other hand, if we require that only certain modules address the security criteria, then we have no assurance that the other modules then will use the security services provided by these specialized modules. In fact, we have no assurance that they won't even undermine any security that those modules might provide.

What we ended up recommending is that whenever an EHR module is submitted for certification that they address all of the security certification criteria in the same way that the HIPAA security rule talks about making implementation specifications addressable. In other words, if I'm submitting an EHR module, I first of all describe whether that particular criterion is applicable to my module and to the environment that it's anticipated to be used. If it is applicable, then I describe how that certification criterion would be addressed. Whether my module is dependent on an external service or whether my module incorporates the capabilities, the point is these criteria need to be addressed.

The second bullet is that in the case of security, this is kind of a flip side of what Jamie was just talking about. In the IFR for security, the preamble to the IFR included a number of example standards, and these were expressed as e.g. for emphasis, and these were SDO standards like AES encryption that were specifically referenced in the preamble, but in the body of the regulation itself, there were no specific standards that were required. The only exception is the integrity standard, SHA.

We actually had some debate about this, whether there should be specific standards referenced in the body of the regulation or if it was best in terms of maintaining flexibility and nimbleness that these standards not be contained within the regulation itself. Ultimately, we ended up recommending that really the body of certifiers that we discussed earlier this morning is really in the best position to maintain a list of standards that are acceptable for meeting a particular functional standard in the IFR, and that was our recommendation, that the certification program incorporate this maintenance of a list of acceptable standards.

The third topic is the American Recovery and Reinvestment Act requires that covered entities provide electronic access for consumers, but the IFR itself doesn't use that term, electronic access. Instead, it uses the term online access. We had some concern about this because online access isn't well defined, and many might interpret that as meaning online real-time access to their electronic records, for example, as their lab results come in to have instantaneous access to that result. Or on the other hand if it means a consumer portal, for example, which is a very nice thing, but that would be difficult for small providers to implement their own online portal.

The second concern that we had was that consumers really want to have a copy of their record that they can print off and take to their doctor or that they can download and have on their PC at home. We really felt that the language around this, not only the language in the IFR, but policy around consumer access needs to be clarified, and we look forward to working with the policy committee in doing that and the privacy and security workgroup.

Encryption was one area, as I mentioned, that was although they had the advanced encryption algorithm as an e.g. in the preamble, in the body of the regulation, they had this functional description of symmetric encryption. Symmetric encryption is where the same key is used to both encrypt and decrypt information. The functional description of the encryption turns out to be so general that I could conceivably develop my

own proprietary algorithm and meet that requirement. We felt that in the case of symmetric encryption that the IFR should specify AES, the advanced encryption algorithm, which is the recommendation of NIST as well.

The second bullet, this really addresses what David Lansky was talking about earlier with respect to the NHIN trust framework and the need for confidence in the exchange partner's identities. The IFR lacked such confidence. It lacked any requirement either from the certification perspective or the standards perspective for authenticating the two ends of a trusted link. When one organization wants to exchange information with another organization, it said that you need to encrypt the link between them, you need to protect the integrity of data between them, but it did not say first you need to make sure that the two ends are indeed who you think they are.

We highly recommended, strongly recommended in several places that both certification criterion and a standard be added for requiring the authentication of both ends of the trusted link before that trusted link is set up. Now, if it turns out the two standards that the IFR, the encryption integrity really we're talking about which is the transport layer security and IPSec both, both of those standards authenticate the ends of the transmission before they establish the trusted link, so we have standards that can do that. We just don't have the certification criterion or the standards in there right now.

Then the final area is accounting for disclosure. We found that there is an inconsistency in the timeline here. The ARRA law itself says that the requirement for accounting of disclosures will go into effect in 2011, but the meaningful use measure says that the meaningful use measure is for 2015. I also want to make sure that I clarify this. Accounting for disclosures is not the same as auditing. Auditing contributes to this, but the accounting for disclosures means that between organizations I … who exchanged information with whom and for what purposes kind of thing.

Right now, and this is for treatment, payment, healthcare operations and right now organizations are not required to account for disclosures of treatment, payment, and healthcare operations, so moving from where we are now to where we need to be is not just a technical issue. It will require significant changes in operations and workflows within organizations. I would also point out that the requirement itself applies only to entities that adopt EHRs, so the net-net there will be that this requirement could serve as a disincentive for the adoption of EHRs because if you adopt an EHR, you have to account for disclosures.

What we recommended ultimately was that we have a discussion between the policy and the standards committees to coordinate a recommendation to the ONC on this topic. We think it really needs to be given a real hard look on how we can implement a very valuable requirement for consumers while at the same time not discourage EHR adoption and not overburden healthcare organizations.

John Halamka – Harvard Medical School – Chief Information Officer

Great. Well, thanks very much for that. Now, has Aneesh joined the call by any chance? Well, why don't I just briefly then go through Aneesh's slide. We recognize, as you've heard, from clinical operations, clinical quality, and privacy and security that there are many standards and policies that need to be adopted by all meaningful users of EHRs. However, there are barriers to adoption. There are tools and technologies that could accelerate and enable adoption. Our implementation workgroup has asked what might we create as a country that would be what we'll call a toolkit, a starter kit that we could hand off to the regional extension centers, to any group that is implementing an EHR or healthcare information exchange to really accelerate their efforts.

I'll give you an example. I at Beth Israel Deaconess recently asked one of my engineers to begin working on some of the interoperability packages that is the content and vocabulary that are necessary for

meaningful use, and he's been working in healthcare IT for 30 years. I said, "Well, what I really need is a start set of LOINC codes that might be used for laboratory exchange. I also would really love a starter set of SNOMED CT problem list codes. I'd like to be able to go to one Web site where I could download every code set and vocabulary that I would need to implement meaningful use transactions without having to go to HL7 for this and CDC for that and the American Medical Association for this." This just highlights one of my engineers who spent 30 years in this domain feels that that is a barrier.

It's clear that across the country there will be such barriers, so let's break down the barriers. Let's ensure that there are the enablers that are necessary, and so Aneesh has been chairing hearings which we had one on March 8 to hear from implementers, to hear from those policy makers, to hear those folks from the federal government that have worked in the FHA context IT implementations to hear what are the resources. What are those starter kit items that would make the job easier? He will continue with gathering that testimony.

Importantly, as we think about a success metric for the work of the HIT standards committee which really is adoption of what we recommend and implementation throughout the country, we created a set of guiding principles as a workgroup. Keep it simple, i.e. make it as simple as possible, but no simpler. Think big, but start small. Building incrementally in phases is likely to get adoption quicker.

Don't let perfect be the enemy of the good enough. Keep the costs as low as possible, recognizing that the Notice of Proposed Rule Making applies to two-doctor practices that may not have an experienced IT staff. Do not try to create a one-size-fits-all standard because it's certainly true that we want to use the fewest number of standards, but have to both address the needs of small practice and the large institutions, so let's just figure out the right smallest set.

Separate content from transmission. This is certainly something that has come out of the NHIN workgroup at the policy committee level. That is, we think of content and vocabulary as going over multiple kinds of transmission vehicles and multiple transmission vehicles can be used for multiple kinds of content. They should be completely separable as capabilities.

Create publicly-available vocabularies and code sets, which you've heard of, is a real accelerator we think in the National Library of Medicine. Jamie's committee taskforce is working on that. Leverage the Web. Of course this is, such as NHIN Direct, we hardly support and I imagine as that NHIN Direct project gets in the implementation phase, that Dixie's group and others will have valuable commentaries in support of it.

Make sure that the quality measures are EHR friendly, that the they don't require paper-based chart abstraction, a lot of manual computation, to make sure that we of course want to measure quality because the whole reason we're doing this healthcare IT initiative is to enhance quality and efficiency, but we don't want to discourage the adoption of EHR by creating such a burden that the quality measures are hard to compute. Support implementers to make sure that we have experts that are available whether those are public or private to assist implementers in healthcare information exchanges in regional extension centers. You will continue to see this committee producing an initial starter kit, and I really do hope that as we hear your commentary on where we can be helpful, the implementation workgroup is able to help meet your needs.

My final slide, and then we'll turn it over for questions, is that the coordination between the HIT standards committee and policy committee should be seamless. Dixie has already mentioned the notion of the workgroups on policy and security getting together. We already know there is cross-pollination and staffing of some of the workgroups, such as the NHIN workgroup, so we're already working together

closely at the workgroup level, but we're very happy to arrange any meetings that you think would be valuable. We want to hear from you as to what are your policy mandates for 2013 and 2015 so we can identify those standards gaps and standards harmonization that needs to be done. We will follow your lead and follow your priorities.

You've heard from the group today that there are a number of issues that we're working on. We do believe that laboratory, especially, needs to start a vocabulary set and very detailed implementation guidance. This disclosure's timeline needs to be worked out between the standards committee and the policy committee so we balance what is a very valuable consumer tool with the reality of implementation. We want to make sure that the right patient summary standards are achieved over time.

In the NPRM it suggests that eventually there be some convergence, 2013 a single summary standard that could be used for multiple purposes, so we want to work through those issues. NHIN Direct, of course, transmission in my view is one of the greatest enablers of interoperability because then many packages will follow once we get all the issues that Dixie has outlined of securing the endpoints and ensuring transport from place to place can occur without modification of the data. Look forward to your questions and look forward to working with you all.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you very much, John. John, I want to let you know that Aneesh walked in about halfway through your rendition of Aneesh's slide.

Aneesh Chopra – White House – CTO
You were terrific.

John Halamka – Harvard Medical School – Chief Information Officer
Good, I was going to say I hope I did a good job. Feel free to add anything you wish.

Aneesh Chopra – White House – CTO
You did it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I appreciate everybody's updating statements to the policy workgroup and wanted to open it up for discussion. David.

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Three things quickly, one is when I talk with leaders from the standards community, the thing that I keep hearing is that they're concerned that there's not enough support and mechanism for refinement which goes along with what David was saying. Basically, after these standards are released, we're going to find lots of warts with them, and they need to be able to evolve, and there's just concern about whether we have in place what it takes to make that work. I think what Jamie suggested takes us in the right direction, but I just think we need to recognize that there'll be a lot of need for evolution within many of these, particularly among the ones that have not been used very much of which there will be some. Second, I just wanted to endorse what John just mentioned about having a single place for things like the value sets because that would just be an extremely valuable resource.

Third, one thing that Dixie said did not make sense to me, and I just wanted to follow up on that. One of the points was that the body of certifiers should maintain the list of acceptable standards. It seems to me like there should be one list of acceptable standards and that having a body of certifiers maintain it, that did not resonate for me.

John Halamka – Harvard Medical School – Chief Information Officer
Let me start off and then I'll turn it over to the others to answer. We certainly recognize that there needs to be not only HIT standards committee work on the selection specification of certification criteria and technical standards, but there will need to be harmonization and commissioning of standards going forward, and so in our committee meeting next week, Doug Fridsma is going to outline ONC's initial ideas about creating a whole new standards harmonization framework, bringing in all those resources, David, that you have mentioned to ensure that as a country we have a whole series of groups moving this forward, dealing with the detailed implementation specifications, and doing it in an organized fashion, a very coordinated fashion.

One of the challenges has been our standards development organizations are great and very well meaning and sometimes domain specific, so you need coordination across all the standards development organization and priority settings. ONC will have a framework for that, so I think everyone has heard about the need for that and that we will certainly be going forward with that. Certainly, on the vocabularies, yes, we certainly concur. Dixie, if you could comment on what you meant by about the e.g.s and why there is a need for a list, but maybe regulation is a bad place to put such a list.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
David, I'm sorry if I was misleading. I certainly didn't mean to imply that there was more than one list. There should be one list, and the terms that we use in our specific recommendation was that the certification program maintain that list. All of the certifiers together with the ONC and with the NIST would work to agree upon a single list of standards that at that point in time would be deemed acceptable. This is completely consistent with how NIST operates in the security arena anyway. They always maintain a list of, for example, the encryption algorithms that are acceptable for federal systems. It would be analogous to that.

John Halamka – Harvard Medical School – Chief Information Officer
I would imagine that the HIT standards committee would of course be working closely with ONC and NIST on having public comment on the items that might be on such a list. I think our challenge is, especially in the world of security, the standards change frequently, and the worry will be that if you bake a specific e.g. into regulation, to David Lansky's point, you actually could inhibit innovation, and sometimes, even, these things are cracked. That is, if we put in a standard that is then shown one month later to actually be vulnerable, that is not going to serve anyone.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, that's how I would phrase in fact, John. It's not that they change frequently. It's that when something goes wrong, they change suddenly which is not really amenable to the regulatory process.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
All right, thank you. David Lansky.

David Lansky – Pacific Business Group on Health – President & CEO
Thanks, I want to go back to the earlier presentation by Janet and Floyd regarding the quality measures. This is a simple question just reflecting my ignorance, but it came up in an NHIN discussion yesterday as well. Is the presumption in the attempt to articulate standards for quality measures reporting that those reports will be generated from an individual meaningful user's EHR platform or that that user will send patient-level data to an aggregator, like an HIE, which will then transmit quality measures to the receiving bodies at the CMS? What does that imply for the standards articulation of that pipeline?

John Halamka – Harvard Medical School – Chief Information Officer
I'll start with that and then ask Jamie for his comments, or is Floyd still there?

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
Yes.

John Halamka – Harvard Medical School – Chief Information Officer
Okay, well, Floyd, if you could tell them about your taxonomy of the five different possible ways this could work so that he feels like, the answer is, David Lansky, yes. It could be that an HIE is or is not involved, an aggregator is or is not involved, and Floyd has a whole taxonomy for this.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
I don't know if I'd call it a taxonomy, but I think that it fits the modular approach whereas the EHR might send patient-level data to an HIE or another aggregator of information which then would, my understanding, as long as that were also certified for that process that that could be meaningful. We're not defining meaningfulness. That's HHS that defines it, but that's my understanding. Thanks.

John Halamka – Harvard Medical School – Chief Information Officer
Specifically, David Lansky, let me just imagine. In the most complicated case, we could have an EHR that sends data to an HIE which routes data to an aggregator which then hires a calculator to do risk adjustment and computation, and then there is a receiver, CMS let's say, that would receive numerators and denominators. We think about that. The EHR could be sending patient-identified detail data to an HIE where the aggregator then maybe deidentifies it or hashes it.

The challenge, of course, is you do need to have some mechanism often of linking data from multiple data sources so that you can compute such a quality measure. By the time that it goes off to be calculated, it's already preaggregated, and then, of course, it's just a numerator and denominator with no patient identifiers sent off to the final receiver, but it could very well be that the EHR could do all these functions, or it could be that the vendor of hospital information systems is the aggregator. All such architectures are possible.

Floyd Eisenberg – Siemens Medical Solutions – Physician Consultant
Just to add, the taxonomy that I think John was referring to is we call the EHRs the data assembly assistant which you would refer to as the aggregator, the processing entity that would calculate and create the report and then send it off.

David Lansky – Pacific Business Group on Health – President & CEO
If I could just follow up, I think the challenge then to the NHIN workgroup as well as perhaps the standards committee is to have a picture of this taxonomy, of this diagram and the layers that John described and then start thinking about the policy implications and the role specifically in the short term of NHIN direct as a means of transmitting those payloads among the parties or not. I think the questions are going to start coming up can we do this with quick and available platforms and standards, or when do we get to tie this in to the CMS reporting infrastructure.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I'll just chime in from the clinical operations workgroup perspective. What we're doing is recommending standards and certification criteria that enable all these functions regardless of where those modules are located in terms of different business arrangements. They could all be within a comprehensive complete EHR, or the modules could be separated in a number of different architectures or entity arrangements.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
On the list I have Paul Egerman, Christine, Gayle, and then Larry.

Paul Egerman – eScription – CEO
Thanks. Paul Egerman. I think it was a great presentation. I have a question for you, Jamie, on your slides. You talked about the family of HL7 and the implementation guide and the implementation guide as a floor which I agree with 100% on the implementation guide, but I didn't understand what you were saying about the family of HL7. You gave the example of 2.5.1, but why can't you specify just as you have an implementation guide floor, 2.5.1 as the floor for that standard and specify it as a floor in order to say that any subsequent revision will also comply with the regulation so that still gives you a way to do revisions and be in compliance with the regulation.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Our recommendation actually is HL7 v2 would be the adopted standard, and that would therefore include all sequential dot release addenda and subsidiary versions of v2, so that would include 2.5, 2.5.1, 2.6, and so forth. They're all different parts of the v2 standard. Then the implementation guide is extremely specific so that it takes one of those particular addenda or subspecifications of the v2 standard and essentially removes optionality by constraining each individual data element, literally hundreds of data elements.

We think both are needed, that adopting the standard at the v2 level allows the industry to migrate from v2.3.1 to 2.5.1. Right now they're working on 2.7. These versions, it's not necessarily possible to meet the same business objectives in 2.5 for example as you can in 2.6. The same thing is true for prescriptions. We look at the migration of NCPDP from the previous versions to 10.6. Well, there are different business functions that are enabled by those different particular specifications of this script standard.

Paul Egerman – eScription – CEO
My question is, is why can't 2.5.1 be the floor? Why is 2.3 acceptable? Why aren't we setting the floor a little bit higher?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think right now, for example, for some of the public health uses, CDC recommends 2.3.1 for a lot of the public health messaging, and that's the state of the art of implementation specifications at the very detailed level for some of the public health uses. That's the only place where I think those are recommended.

Paul Egerman – eScription – CEO
But don't you run the risk that somebody using 2.3 for other purposes, then that makes our interoperability challenges harder?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I'm not sure I follow the question.

John Halamka – Harvard Medical School – Chief Information Officer
Let me answer, Jamie. Paul, the idea is, of course, we want to get to 2.5.1 as a floor for everything if we can. On specific public health data exchange, the CDC's current implementation guide, which is quite detailed and eliminate a lot of optionality, is at 2.3.1. We've tried to be specific to say for this particular purpose, an immunization exchange, it's 2.3.1 using this CDC implementation guide and the CBX vocabulary. Beth Israel Deaconess, for example, is really going to try hard to get to 2.5.1 because we

think that the CDC will be very shortly giving us all the additional guidance we need for that standard. It's just it's not ready yet, and therefore, for the regulation as written as of January 13, we had to go with the implementation guide they did have ready.

Paul Egerman – eScription – CEO
But what I'm suggesting, John, is 2.3 should work fine for immunization and for CDC. You can call that out, but for everything else, 2.5.1 should be the floor.

John Halamka – Harvard Medical School – Chief Information Officer
Correct, and Jamie, comment on that from your experience?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, but I think that's in line with our recommendation. The intent is to set a floor of generally implementation specifications, for example, for lab at 2.5.1 which I think is consistent with the recommendations of this committee, but the 2.3.1 is only for those public health purposes where CDC has defined the state of the art at that level.

Paul Egerman – eScription – CEO
Thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Christine.

Christine Bechtel – National Partnership for Women & Families – VP
There are no decimal points in what I'm going to ask which is good. I have actually two questions, and I want to come back. They're both something that Dixie Baker said. One is about consumer access to information. Dixie, I think as we looked in the meaningful use workgroup at the future of where we want to go, there's no question in my mind that it's ongoing, online, real-time access to information. I think that's not clearly where the 2011 NPRM is.

My question is, knowing that that is a challenge right now for small providers but yet that's where we need to go, what's the role of the health IT standards committee in helping us move towards that vision. I'm thinking of ideas that have surfaced recently, including creating some sort of a button that is very easy for patients to click on from a PHR or a portal or a platform that's going to pull data from an EHR in a standardized way. That's going to require (a) standards, (b) certification, getting it in the pipeline. I'm just kind of curious what role that the standards committee can play in helping us move toward a vision of ongoing real-time online access to information for patients and their caregivers and then whether there's anything you might need from the policy committee to move in that direction.

Aneesh Chopra – White House – CTO
Christine, perhaps I might take this one. Dixie, if you want to chime in, that'd be great. That is in many ways why we have the implementation workgroup. We had a public hearing not even a week ago (I don't know what day of the week is today, Wednesday?), Monday last week, and the entirety of the meeting was basically what you could do to pull forward a lot of the provisions.

Obviously, the consumer access to information stood out as one of those criteria that, if I would paraphrase the providers, had not been in the requirements document, their traditional IT procurements I guess is my paraphrasing. There was a great deal of interest from the federal agencies who testified. I'll call out specifically the National Cancer Institute which publicly declared that it would provide consumer access, reference implementation, and support tools so any provider, they're working with a whole

panoply of electronic health record vendors in the cancer community specifically to enable dual purpose, both providing information to the patient and to provide information for research purposes. In fact, that was part of the testimony was to sort of catalogue all of the various tools that will be made available to bring forward and ease the burden of the implementation of those provisions. There was a great deal of interest in the room about pulling and leveraging some of those assets.

I would also suggest that the NHIN Direct in a sense, David, you may have said this before I walked in the room, but in a sense a significant part of the early collaborators who signed on to participate in that endeavor are doing so with consumer use cases in mind. My presumption, again, is the standards committee with the implementation workgroup will gather input that will help us as we think about work for 2013, but along the way with the implementation starter kit, there'll be this shared ability, the reusability of intellectual property that I think will help to address the policy vision that you've articulated with an on-the-ground reality. Is that fair, Jamie? Dixie, did you want to comment beyond that?

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes. I think that what we need to do first of all is the policy committee needs to define what electronic access per ARRA really should be because the requirement itself is not clear. The ARRA says electronic access which could be met quite frankly with popping a file onto a USB drive. Truth is for those small providers out there, that might be the best that they can do, and it's still better than giving them a Xerox copy of 50 sheets of paper.

I think what we need here is really a roadmap that starts out where do we really want to be and how do we get there. What are the steps we need to get there reasonably? I also think with respect to Aneesh's comment about implementation, the MCI, for example, their whole approach is through the PHR, and I think that we need to think through these different models of providing users access to their information so that it's convenient and also safe from a liability perspective to the provider.

There are lots of factors there. I think we need to define where we need to be from a policy perspective and a roadmap toward that, and the standards will be there. I don't think the standards themselves are the issue. I think policy is the issue.

Christine Bechtel – National Partnership for Women & Families – VP
I think it might be helpful, and I can followup offline, to understand more about what you mean about defining the future because—

Aneesh Chopra – White House – CTO
I don't want to speak for your policy priorities, but in the President's commitment to an open government, we have defined access to information as essentially providing it in machine-readable format. That was a policy statement that the President has made so that when we release information on our Web site, data.gov, the whole purpose of it is to allow for the reusability and frankly the innovation that comes from being able to consume that information and actually build innovative applications on top. That's our priority. Your advice to the President and to David Blumenthal clearly would be your own deliberation about what that means, but we have a clear vision for how we're handling open government and would welcome your input.

The provision to allow access to the information is extraordinarily exciting. It's in line with the vision. Maybe what Dixie's saying is language like we use in the White House, access to machine-readable format, might be a little bit more meat, and then the next further meat is if the discussion actually says, well, in fact, with this metadata, and then it starts to get a little bit more detailed, but maybe it's a little

more fuzzy right now. Maybe we can move a little bit further. Those are the judgments you all have to make, but I think the machine-readable would be the next logical deliberation point if I may say.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
We had a lot of discussion about exactly that, Aneesh, and the truth is it needs to be in both human readable and machine readable because if I provide an XML document to a consumer, and they see a bunch of XML tags, they're not going to be happy with that.

Aneesh Chopra – White House – CTO
Dr. Ondra would love it. He's looking at me right now. He's like, "I read XML all the time."

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
But that's a perfect example of the kinds of things we discussed and that need to be addressed, Christine.

Christine Bechtel – National Partnership for Women & Families – VP
That's helpful, and maybe we can … for the patient engagement hearing that's coming up as well. My other quick question is about consent management. Dixie, I'm wondering if you can help me remember, and I may be not recalling this correctly, but over I think it was the summer ONC released a set of standards for public comment that were around I thought it was consent management. I'm not sure whatever happened with those and how that relates to the work that you're doing to bring your workgroup up to speed in this area.

Dixie Baker – Science Applications Intl. Corp. – CTO, Health & Life Sciences
Yes, that was a document on consumer permission's management, and that certainly is one of the documents that's there as a resource, but it's not a standard. There are no standards there. It's really a discussion of permission's management.

Christine Bechtel – National Partnership for Women & Families – VP
Perfect, thank you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thanks. Gayle.

Gayle Harrell – Florida – Former State Legislator
Yes. Gayle Harrell. I think Paul pretty much covered what I had wanted to ask specifically about interoperability. I have a great deal of concern that by not being specific, by not going to HL7 5.1 or whatever we need to do, we are going to go down the road that we've been on for so many years where you don't have interoperability.

I see in Florida as we're getting our HIE stood up and we're having many of them start to really exchange information the cost of interfaces, and the vendors are charging each physician $5,000 or $10,000 to connect to the HIE to develop an interface for each lab that they connect to. Yes, you want innovation. You want change. You want to be able to progress, but we also need to do it in a way that at each stage the vendors have to meet specific standards so there is that interoperability.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
We couldn't agree more. I think from our perspective we see a clear need for completely detailed comprehensive implementation specifications that provide guidance on the use of these standards to achieve interoperability. That's absolutely required. The question is how those implementation

specifications should be promulgated. How should they be made available to implementers for purposes of meaningful use?

We think that's where the IFR got it wrong because 2.5.1 is not a sufficiently detailed specification to enable interoperability by itself. Essentially, the way the IFR is written guarantees a lack of interoperability, so we do need specific implementation guidance for the use of that standard. The department chose not to put that in the IFR, and so we're recommending an alternative mechanism of making that available. At the same time, we're trying to address the companion problem of how do you advance the standards from 2.5.1 to 2.6 to 2.7 and on, and so that's why we're saying if you constrain it in regulation to v2 and then use this alternative mechanism for implementation guidance to advance from the floor of 2.5.1 up to subsequent version, that could be an effective alternative framework.

David Lansky – Pacific Business Group on Health – President & CEO
If I may comment, again, David Lansky, I don't know how much you've already covered this, but my presumption is that the NHIN Direct framework in many cases is going to assist in that problem. The notion of the cost of participation for physicians and hospitals by virtue of the fact that we have these point-to-point interfaces as the predominant means of interoperability in communities throughout the country, we are laser focused on working that particular problem. You see this in the mosaic of activity. Somewhere in your hearing you're going to have a discussion of the CLIA guidance. Tony, you're going to sing the happy tune about where we're going on CLIA guidance.

On all the component parts that today make up some of the complexity and the cost will, I believe, through initiatives within the NHIN more broadly, very specifically in the Direct, the guidance … all will speak to decreasing the cost for providers so that we can bring operability as the first order of condition while we bring in the interoperability framework. I think A, B, and C in harmony is sort of how this is proceeding. I don't know if you've already covered this ground, and forgive me if I'm repeating it.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Larry.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Congratulations on the great work you've been doing and the collaboration with this policy committee. One of the areas where I thought we could extend that collaboration would be with the work that the implementation subgroup workgroup is doing. It seems like it lines up really well with the workgroup on adoption and that that would be a place where we could coordinate some things.

Aneesh Chopra – White House – CTO
Like a hearing, perhaps, on something of shared interest. It'd be wonderful.

Larry Wolf – Kindred Healthcare – Senior Consulting Architect
Thanks.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Also, one more comment having to do with Janet and Floyd's testimony in terms of the measures and Janet's call for more measures that would be EHR enabled or EHR sensitive, I think that's something we haven't paid quite enough attention to. I think the biggest motivators for the folks we're trying to influence (doctors, nurses, clinicians) would be to have meaningful measures that they can relate to, that the professionals can relate to. Right now just our history has been limited to building data and just like we're trying to get ahead of the curve for vendors in the criteria, we need to get ahead of the curve for measure developers to provide measures that we can actually report on and have meaning to all of us including

patients. That's something I hope we sort of bring into the fold as well as we go forward. Thank you very much to the HIT standards committee.

John Halamka – Harvard Medical School – Chief Information Officer
Thanks very much, Paul. It's just been a pleasure working with you.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thanks. Then we'll turn it over to Tony who I'm sure is going to report on the love letters he's received in the past week.

John Halamka – Harvard Medical School – Chief Information Officer
You guys have a great day.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you.

Tony Trenkle – CMS – Director of OESS
Good afternoon, everyone. We're in the first phase of our version of March Madness as we and ONC move towards our four final regs, and it's been quite a process so far. At this point the comment period is closed. The public has spoken. We've gotten over 2,000 comments. A few more may come in over the next several days. Once we waded through the government is evil ones which we figured were misdirected to us instead of should have been ONC's, but—

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We got a few of those, too.

Tony Trenkle – CMS – Director of OESS
We found there are a number of themes that are starting to come out. Now, this is all premature. We haven't physically gone through all the comments. There's a little bit of a lag period for getting them. They come in through a variety of venues, including regulations.gov, and those of you who tried to upload comments know that that can be challenging sometimes.

We should have a pretty good handle on them over the next couple weeks as we go through them. What we do is we read them. We analyze them. We prepare a comment in response. We draft issue papers on the higher level policy issues that need to be dealt with, and of course, we go through a process of clearance, both through HHS and through the Office of Management and Budget. As you know there's a lot of interest not only outside the government, but also inside the government, so there's be a lot of input in the NPRM. The Secretary was very interested as were Peter Orszag and some of the policy makers at the Office of Management and Budget. I'm sure they'll be interested as well as this process goes along.

All the issues in the NPRM have to be addressed with a comment response. We tend to group them with patterns. We look for rationale. We look for data. We look at them in terms of statutory policy and operational how much they fall into those things. If somebody recommends a change that's outside statue, obviously we can't do that. If it requires a major policy decision, then we'll try to float it up through the ranks of the policy makers. Of course, operationally, we have to look at the operational feasibility of some of these suggestions as they come through.

We've received a lot of thoughtful comments. I want to thank the policy committee for the work that they've done and the letters that were sent to David and they came to us. I think they reflect a lot of thought. The comments that I've looked at from a number of organizations also reflect a lot of thought, a

lot of balancing which of course we have to do, which is balancing getting this program off the ground. We're trying to meet the larger policy goals, many of which we've talked about in this committee.

I think that the NPRM also reflected a direction that we need to get feedback on. Of course, with the NPRM we go at it a little more aggressively than we do in a final regulation because we try to push the envelope. It also reflects the thoughts of various policy makers within the administration, so let me give you just the sampling of some of the comments we've gotten so far. As I say, we haven't gone through the entire 2,000 of them. People have looked at probably half of them at this point. We will be probably compiling a more complete list. Then if we're here in April, well, if we survive to April, we'll come back with maybe a more comprehensive report.

In general, comments have come in asking to lower the bar or asking for additional clarification on objectives and measures. Some of this clarification can be handled below the policy level. The whole issue of meaningful use flexibility, which of course came up time and again with the policy committee. That's been a nearly universal requirement to earn the incentive. There have been various suggestions about how that should be done, setting it as a percentage of measures that must be met, setting some measures as core and others as optional, scaling the amount of incentive payment to the level of completion of meaningful use which we can't do (That's a statutory issue.), reducing the number of measures, reducing the number of clinical quality measures, reducing the thresholds of measures. These have been common themes that have come out through all the different groups that have commented.

The second issue is the issue of the denominator where we can't capture information through the EHR or where it becomes a manual process. We got a lot of comments back on that. The issue of counts versus percentages, this was one that a number of the provider groups weighed in on in terms of looking for that. There was a lot of pushback from what we've seen so far on the administrative measures. A number of organizations came in and said we don't feel that they should be part of this.

Of course, the concerns about CPOE, as we know that's been a common theme from the hospitals in particular. A number of organizations in and expressed concern about allowing the states too much flexibility in terms of making changes to meaningful use criteria. Then of course there were specific comments on objectives, many of which have been talked about here, the patient education resources, … directives, progress notes, stratification by demographics.

Probably about 80% of the comments have been specifically focused on meaningful use of quality measures. There has not been as much comment that we've seen so far on the impact analysis or some of the specific programmatic language that we put into the reg. In the quality measures it was the issue about avoiding redundant reporting, limiting the measures to those already on track to be EHR ready, clarification of measures, clarification questions on whether we should have core measures or not. There was certainly some question about how many measures from a quality standpoint should be met early.

Of course another area that was discussed is the whole signaling area, how much should we be signaling for future stages. Some folks have come in and said you should lay out the whole program now in the regulation. You should lay out what objectives you want to achieve by 2017. That's been a theme from many of the hospital associations.

Speaking of the hospital associations, of course, the definition of hospital-based eligible professional has been a big topic, the definition of hospital identification, dealing with the whole issue of multi-campus hospitals, whether they should be separately identified and given payment. Then the length of the reporting period for the second year, people were happy with the three months for the first year. There was some discussion about the second year.

These are pretty much kind of the early feedback we've gotten. There's a lot more detail and a lot of comments. One of the things I thought that was good, a number of you came together and gave us comments rather than everybody commenting separately. Even though we got 2,000 comments, that was very helpful to say, okay, this is the point of view from an organization. For example, the AMA came in with a number of the specialty associations, and the Markle came in with a number of organizations together as well, so that's been helpful in helping us take a look at some of the comments and seeing some of the patterns that emerge.

Where we go from here is once we categorize these and begin to tease out the high policy issues, develop the comment and response, then we can pull together the shell of the final regulation and try to work on a parallel path to get some of the policy issues discussed early on by some of the people at HHS and at OMB at the political level and then move towards a final regulation. The deadline we haven't set yet, but we'll have to see how long it takes to pull this together and get some feedback. We're probably looking at late spring at this point which could be impacted depending on whether some of the issues need further clarification or there becomes an issue where we're getting comments come in maybe evenly divided as to whether to do something or not to do something and we need to discuss that or certain policy issues that were pushed by people at certain levels of the administration. We'll have to have some conversations with them as well.

That's where we're at now. We're glad that the comment period is over and that now we can begin to level set this against what we put in the NPRM and see where we need to go over the next couple months, but once again, thanks for all the work that you've all done, both as members of the committee and also outside the committee. It's been very helpful in terms of setting a bar and setting criteria that then can be measured against. It's certainly much easier to take something that's in an NPRM that's laid out the way it was laid out and then measure against it for the final than something that's not quite as well organized and thought through, so Steve, do you want to talk about your?

Steven Posnack – ONC – Policy Analyst
Sure. Steve Posnack again from ONC. This'll be the update on the Interim Final Rule on standards and certification criteria. We got about around several hundred comments. All of the ones that are specifically relevant and in scope to our rule have been posted to regulations.gov. That's approximately in the low 300s, so we were not as fortunate as CMS with respect to the number of comments, but they are all just as important, and a lot of them are from the standards development organizations and colleagues of yours out there. We, again, want to thank you as well for the thoughtfulness and the comments that we received.

Everything, I guess, like Tony said is preliminary at this point. I think they may have gotten tired reading CMS's rule before they got to our rule which may account for some of the drop off in the amount of comments, but there were a lot of comments around the specific standards. The presentation you got before is kind of a precursor to a lot of the standards that were reflected, another request for coordination with CMS which we will absolutely be doing. Then, as Tony mentioned, there'll be a lot of policy decisions that need to be made. We will be kind of doing the one-two step with CMS with respect to the objectives and the certification criteria. As policy decisions get made with respect to meaningful use, we will try to reflect them in the certification criteria and standards that we've adopted.

I guess what I'd like to point out just for awareness factor is that if flexibility is introduced or considered, that may not be something that we could reflect in certification because if you allow people to pursue different capabilities using the technology, the technology still needs to be able to provide all those

capabilities to support the different flexible uses. If there are areas where flexibility could be provided, we may not be able to provide that for certification.

The other thing that might be helpful in terms of a contextual perspective is the internal choreography of the Interim Final Rule which is a lot more complicated than it seems just on face value when you're reading it because if you look at it in the scope of just meaningful use it seems pretty straightforward, but internal to the reg text requirements, we have to balance other regulatory requirements for HIPAA code sets and transactions that meaningful users need to meet because they're covered entities. Part D requirements for electronic prescribing that also need to be met and there are specific regulatory requirements where NCPDP script is specified, so we need to balance that in. HIPAA privacy rule requirements for accounting of disclosure which we were require by statute to adopt a standard for before the policies were specifically established. We trigger OCR's regulatory processes, and that's described in the rule and kind of the balancing act that we had to go through. Then other HIPAA security requirements to make sure that the EHRs provide the capabilities to support the HIPAA security rule.

One of the things that we may have to deal with is what's in scope and what's out of scope and how we need to balance the other regulatory provisions that we need to keep in mind and keep abreast of so that we don't require something in our rule that's contrary to another HHS regulatory action which is something that may look very interesting with respect to timing of certain standards and what people are required for. Scope I would assume is going to be one of those things where in our comment and response we will try to be as clear as possible what is in scope and what was out of scope and why we couldn't take a particular action.

Then building off of the presentation you got before was helpful for me to hear again some of the concerns that were raised. I think it's important for people to keep in mind that this certification criteria and standards that we've adopted are for certifying the products and not what organizations need to meet. There's a little bit of a difference there in what the approach is and what the certification criteria and standards are for and that some of these will be certified independent of the operating environment that they're implemented in. We have to take into consideration a lot of those factors and where things are going to happen.

Tony Trenkle – CMS – Director of OESS
I think to follow up with Steve is we talk about the four final regs and pardon the analogies, but there really is a dance between the four final regs because people look at the IFR and our reg as being closely linked, but also, the certification NPRM is really one that the two final regs that come out of that are ones that really have to sync with our program because from an operational perspective, understanding what a certified EHR is and someone being able to attest to that and then for us to go back and audit that that is a certified EHR means that all these four regs really have to sync together, so we're closely linked with our fellow colleagues from ONC whether we like it or not.

Steven Posnack – ONC – Policy Analyst
It's exciting to be a part of a very nontrivial exercise to go through, and the more policy issues there are, as somebody raised, the more complicated getting a final rule is.

Tony Trenkle – CMS – Director of OESS
Right, it does create some complications. When you start talking about flexibility, I understand that from a conceptual standpoint, but then you have to translate that into operationally feasible, and that's where you really have to begin to start looking at the interplay between the regs and also the interplay between that and making a January 2011 date for operational because the more complexity you build into this process, the more difficult it becomes to launch a program quickly and efficiently. As I say, there are a lot of good

comments, and we're looking forward to continuing the dialogue with you and others over the next several months.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Any quick questions? We're a little bit on time. Christine and Art.

Christine Bechtel – National Partnership for Women & Families – VP
Christine Bechtel. I was just curious from your characterization, Tony, what people said that they liked in the rule. I know we submitted, like, 13 pages of we like this stuff that more than 20 consumer groups signed on, but I'm wondering what folks said they actually liked.

Tony Trenkle – CMS – Director of OESS
I think people liked the approach. I think they liked the fact that we laid it out in a matrix that really laid out how we're going to be looking at the objectives and measures. I think the biggest issue was not the way we laid it out, but the speed at which it's implemented and the amount of how we set the bar, not that we have the bar, but how high it was set. They like the approach, but the question was how quickly do you need to go through this approach. Of course, the other issue was the eligibility of certain professionals and others for the program. I think there was overall pretty good feedback. It was well thought out and the approach was definitely what was needed.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
I certainly would like to second that. I think it was an outstanding effort in terms of what CMS and ONC have put together in the past year. It's just an incredibly rich set of programs, so thanks for all your work. I guess we're empathizing with you, so we run our meetings without breaks just like your life I think, so thank you very much, Tony and Steve.

Tony Trenkle – CMS – Director of OESS
Thanks, Paul.

Steven Posnack – ONC – Policy Analyst
Thanks.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Our final discussion before the public comment is CLIA discussion, and it's Jess.

Jessica Kahn – CMS – Project Officer
I'm here.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Great, take it away.

Jessica Kahn – CMS – Project Officer
Hello, everyone. Lovely to stand between you all and lunch, so I will try to keep this fairly short so that in case there are some questions we have some time for that. On March 1 CMS issued our most recent CLIA guidance on the electronic exchange of laboratory data. If we go to the next slide, I'm going to just give you a real quick recap of what led up to that, and then I'll get into what the memo was covering.

Over the past, this has actually been ongoing work for several years, and I don't want to belittle that, but within the past six to seven months it has been raised to senior leadership both at ONC and CMS as potentially a barrier to the exchange of laboratory data, and so the IE workgroup, Micky and Deven, very

graciously agreed to have a hearing specifically on this, and they brought in the various sizes of labs, the EHR vendors, health information exchange folks, providers, and some policy experts, and it was a very rich hearing. Of course, all that information is public. From that we took what was said and what we learned and put most of it into the CLIA memo, though some of the recommendations that were generated also relate to EHR standards and certification, so this only covered what was in the purview of CLIA.

As I said, it was just issued on March 1. The audience for this I think it's important to note so that everyone's clear who has it directly, and that's all the federal and state CLIA staff within the CMS purview and the state, state Medicaid directors, and then we also c.c.'d the state HIT coordinators that have been identified under the ONC HIE cooperative agreement. We wanted everyone on the same page, and we're going to circle back to the same audience to have a followup call later in April to see what questions they have.

The key issues covered in this memo, these are the key points. First of all, there was real emphasis on explicitly clarifying the role of HIT within the existing CLIA regulations. Because of its absence in the text, there were some misperceptions and thoughts about what that omission meant, and so we went though and everywhere that it was relevant explicitly defined what the role of HIT would be. It also addressed the use of departmental and federally-recognized standards and specifications to support laboratories compliance with CLIA. The last primary issue that it addressed was clarification of patients' access to lab results.

This is just an example of some of the things that were highlighted that may have seemed intuitive, but as I said, we had to make it explicit in this new age of HIT&E. First of all, the transmission of lab data through a health information organization is expressly permitted. If it's on the laboratory requisition, then an agent of that authorized person, be it EHR vendor or an HIE or so forth can receive the lab results directly on behalf of that authorized person. A laboratory can contract with another entity to facilitate the delivery of those patient reports. Again, this is something in our HIT&E area that wasn't normally conceived of under CLIA.

Then one of the primary concerns that had been raised to ONC and CMS leadership was the burden for verification that the results were transmitted in an accurate and timely way when transmitted electronically. We clarified here that CLIA does not require visual inspection of each EHR installation. CLIA actually doesn't specify how often or how you verify the accurate transmission of lab results, just that you must do so. We put in here in several places in this memo a very important statement which is that we anticipate that labs adoption and use of departmentally-recognized standards such as HL7 2.5.1 and LOINC and the NHIN specifications would reduce the laboratories' frequency for verification of the accuracy of the transmission of results. In other words, this is their shortcut to getting there in a cheaper and more cost-efficient and easier reliable way.

Patient's access to lab results, again, we needed to clarify some issues here. There has been actually a lot of summarative work done outside of CMS and ONC on this. Both Georgetown and NASHP, the National Association for State Health Policy, did some work for the California Healthcare Foundation. All of these papers came out at the end of the year or at the beginning of 2010 and really gave a good overview of how this plays out in the states. We wanted to clarify in our interpretive guidelines in what scenarios under CLIA a patient can receive their test results directly. That has to do with whether they're an authorized person or whether they can be considered an individual responsible for using the test results, and we clarify where state laws might have some interplay there.

Here are some of the remaining gaps and next steps, and these are just very broad brush strokes. There's probably more. Sort of in the short term, this is new for a lot of the CLIA staff and the regional office folks and even in some of the states, so this guidance is what the surveyors use to go out there and determine whether laboratories are compliant, so we really need to sure they understand and are applying this new CLIA guidance correctly, so that's our immediate short-term goal.

At the same time, we have some larger policy issues that we want to look at. Particularly patients' access to their lab results within the confines of HIPAA and CLIA has been identified as a shared policy goal, so CMS and ONC and the Office of Civil Rights are going to work on this within the context of all of our regulations and state laws and how to facilitate patients' labs and providers' understanding of what patients' rights might be. Again, I pointed out that there have been some good summary documents out there, so we need to work to make sure everyone has access to those as well, then the larger issue of how to facilitate laboratories' use of the standards and address other barriers that the IE workgroup noted from the hearing, such as a lack of laboratory data compendium, those sorts of things.

We also wanted to point out to everyone that as these policies evolve, as there's more maturity in the standards and practices in the exchange of health information, laboratory information, we will revisit our CLIA interpretive guidelines. This is a dynamic document. This policy goes into effect in the letter as soon as the letter is out, and so we can update our FAQs and our guidance as need be as any of these particular issues that I highlighted become clearer. With that I'll take questions, and I think Jon Ishee and some others from ONC are probably in the room and can help field questions as well.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Okay, question from Mike.

Mike Klag – Johns Hopkins Bloomberg School of Public Health – Dean
Mike Klag from Hopkins, I was at the October meeting and heard the testimony from the vendors, and I have to say you've done a phenomenal job responding to the concerns that were raised and in a very short time, especially the issue about, it's amazing to hear to dissonance between what the CMS rep said at that meeting and what the vendors' interpretation of CLIA regs were, and especially this issue about not requiring visual inspection of each installation, so it's great. I'm wondering is this memo, is it available to the public, or can the committee get a copy?

Jessica Kahn – CMS – Project Officer
Absolutely. Micky Tripathi and Deven McGraw both have copies. The whole IE workgroup does. We can make it available. It's also on the CMS Web site. If you were type in CLIA guidance, it would pop up for you. It's very much public domain.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thank you very much, Jess. As you mentioned it's been work that's been ongoing, but it appears to have come to a head and very quickly reacted to the concern of the industry in terms of meeting the meaningful use objectives and the overall patient objectives, so thank you very much. Now, we can open it up to the public. Are we ready?

Judy Sparrow – Office of the National Coordinator – Executive Director
Yes, we are, but I've lost the slide there, so operator, you'll have to read the telephone number. Anybody in the audience? Anybody on the telephone?

Operator
We have a comment from Robin Raiford.

<Q>: Hi, can you hear me? This is Robin Raiford.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
We can hear you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Yes, we can.

<Q>: Good, I promise to not talk more than three minutes. Thank you for the lively discussion today. I just had a couple of comments after listening today where someone brought up Captain Sullenberger talking at him, and I wanted to pass on something that didn't get said when he was talking about how astonishing it was that in the aviation system that you had to follow a checklist and what you had to do, and one thing he shared at the end was he said he hoped that medicine would get it right and make the changes and that we would what's right because it's the right thing for our patients, that our colleagues would expect it, and our profession would demand it.

I hope that in all the government is evil comments and that sort of thing that Tony talked about that somebody will remember at the end there are patients here dying every day waiting for change to happen and that in the ten years since the IOM study if people were going to do it on their own they would've done it and that organizations have three years to get to stage one and still receive all four of their payment. Like John Glaser has said, this is a voluntary program. If you're not ready, then don't sign up just yet.

I also wanted to thank Deven McGraw and Christine Bechtel and also Representative Harrell for just remembering the patient in all of this. The patient is the ultimate recipient of meaningful use and what can happen. If ONC needs to step in and be the voice for the people who've died, then that's what needs to happen because clearly voluntarily it's not happening in this country.

I have one other suggestion as a followup to an innovation meeting that was quite lively at HIMSS that Aneesh Chopra and Todd Park hosted. Perhaps an idea for HIT policy committee is to have something on the blog or a way to reach out to like patientslikeme.org or some of those consumer organizations or one that Nancy Davenport … chairs about getting comments from the public about I wish my doctor's EHR could do this to help coordinate my care because clearly people on patientslikeme.org are so desperate for coordination. They just put their whole medical record out there you can find on Google, and they don't care, and that's my comment for today. Thank you so much.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Robin. I believe we have one other person on the phone.

Operator
Our next comment comes from …. Please proceed with your comment.

<Q>: Hi, this is …. I hope you can hear me. First of all, I want to express my awe of the work that the committee and ONC and all the work that they're doing and all these enormous processes that you guys are putting in place.

My comment goes to the role of NIST in the certification process. From what I understood today from Carol's slide, they were pretty much rewriting the test procedures, and I did look at the … procedures on

the Web over the weekend, and after going through three or four of them, I needed to sent an email to NIST. Unfortunately, I haven't seen any changes.

Here's the problem. I believe NIST is currently lacking in the expertise required, and it should be reinforced before we go any further because, for example, if you look at the test procedures of something as simple as maintaining a medication list, it turns out that if you go and modify it then you pretty much obliterate the history of all the medications. If you had a patient on warfarin that you've been managing for a year or two and you happen to change the dose or frequency today, according to the test procedure, that overrides the entire history of the warfarin that was administered.

That's … patient safety as well, and I'm sure there are audit logs and so forth, but no physician is going to examine audit logs when he just tries to adjust the medication. This is just an example. There are a lot more in there. There's no accountability or recording of why changes are made and … diagnosis and so forth. I think there needs to be a little more. I recognize these are drafts, but I think there needs to be a little reinforcement or major reinforcement in the expertise regarding EHR medical records that is currently … NIST. That is my comment. Thank you very much.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you very much, and I'll turn it back to Dr. Tang.

Paul Tang – Palo Alto Medical Foundation – Internist, VP & CMIO
Thanks. I'll just echo the last speaker's comments about standing in awe for the enormous amount of work that's been going on in ONC and in CMS and the rest of HHS and awe and gratitude for the members of the committee and the workgroups that have been putting out so much that really has I think contributed greatly to all of this work, so thank you very much and see you in April.

Public Comments Received During the Meeting

1. Please have the CLIA guidance include transmission of LOINC codes with lab results.

2. Thank you, for organizing this. The slides are clear and bright, and the audio is similarly excellent. Often, webinars are horrible exercises in techno-nonsense. Nice job HHS...

3. For Comments on the IFR and Standards, to the point on clarifying vocabularies, can we get clarification on the Public Health Requirements. Specifically as to Reportable Lab Results, and Syndromic Surveillance. What values are considered reportable? What specifically should be in the data stream as a syndromic value? We understand how to code HL7 2.3 or 2.5.1, but clarification of what belongs in the stream is needed. Also, will each state have their own measures and thus make it very difficult of national vendors to deploy and keep track of all the flavors of Public Health Reporting. CDC should take the lead here and since the states receive Federal Support, they should comply with a federal boilerplate. Again thank you.

4. From a vendor perspective, are we to assume that we would demo the product(s) twice ? First to some representative from the Lab and then again for the Certifying body. Thank you.